

**Agenda for Quarterly Meeting on MDUFA III (FY 2013-2017) Performance**  
**April 29, 2014**  
**10:00 A.M.**

**Welcome.** *Barbara Zimmerman, CDRH-ODE.*

**Guidance Development**

- *Philip Desjardins, CDRH-OCD.*

**FDA MDUFA Performance — Actions through March 31, 2014**

- Report on decisions goals for 2nd quarter of FY 2014.
  - CDRH: *Barbara Zimmerman, CDRH.*
  - CBER: *Sheryl Kochman, CBER.*

**Qualitative Update on Finances – 2<sup>nd</sup> Quarter of FY 2014**

- User fee receipts through the 2nd quarter of FY 2014. *David Miller, FDA-OFM.* **CDRH**

**Registration and Listing**

- Report on registration and listing- *Dave Gartner, CDRH- OC.*

**CDRH Training**

- Report on training- *Barbara Zimmerman, CDRH.*

**Independent Assessment**

- Progress and update- *Amber Sligar, FDA-OC.*
- CDRH's Plan of Action in response to BAH MDUFA II/III Evaluation Priority

Recommendations: *Jeff Shuren and Nancy Braier, CDRH-OCD.*

**Set date for next meeting, following close of Q3.** Target Date: Tuesday - 7/29/14 at 10:00 am.

## Medical Device Guidance Documents

### Issued in FY 2014

(January 1, 2014 thru March 31, 2014)

1. [Medical Device Tracking - Guidance for Industry and Food and Drug Administration Staff](#) (03/27/14)
2. [Premarket Assessment of Pediatric Medical Devices - Guidance for Industry and Food and Drug Administration Staff](#) (03/24/14)
3. [Premarket Notification \[510\(k\)\] Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery - Draft Guidance for Industry and Food and Drug Administration Staff](#) (03/24/14)
4. [Premarket Notification \[510\(k\)\] Submissions for Electrosurgical Devices for General Surgery - Draft Guidance for Industry and Food and Drug Administration Staff](#) (03/24/14)
5. [Humanitarian Device Exemption \(HDE\): Questions and Answers - Draft Guidance for HDE Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff](#) (03/18/14)
6. [Administrative Procedures for CLIA Categorization - Guidance for Industry and Food and Drug Administration Staff](#) (03/12/14)
7. [Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff - Guidance for Industry and Food and Drug Administration Staff \(PDF - 297KB\)](#) (02/18/14)
8. [Questions and Answers about eMDR - Electronic Medical Device Reporting - Guidance for Industry, User Facilities and FDA Staff](#) (02/14/14)
9. [Annual Reports for Approved Premarket Approval Applications \(PMA\) - Guidance for Industry and Food and Drug Administration Staff](#) (02/10/14)
10. [Class II Special Controls Guideline: John Cunningham Virus Serological Reagents - Guideline for Industry and Food and Drug Administration Staff](#) (01/24/14)
11. [Medical Devices Containing Materials Derived from Animal Sources \(Except for In Vitro Diagnostic Devices\) - Draft Guidance for Industry and Food and Drug Administration Staff](#) (01/23/14)
12. [Reporting of Computational Modeling Studies in Medical Device Submissions - Draft Guidance for Industry and Food and Drug Administration Staff](#) (01/17/14)
13. [Custom Device Exemption - Draft Guidance for Industry and Food and Drug Administration Staff \(PDF - 248KB\)](#) (01/14/14)
14. [Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use - Draft Guidance for Industry and Food and Drug Administration Staff \(PDF - 521KB\)](#) (01/07/14)
15. [Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Draft Guidance for Industry and Food and Drug Administration Staff \(PDF - 524KB\)](#) (01/07/14)

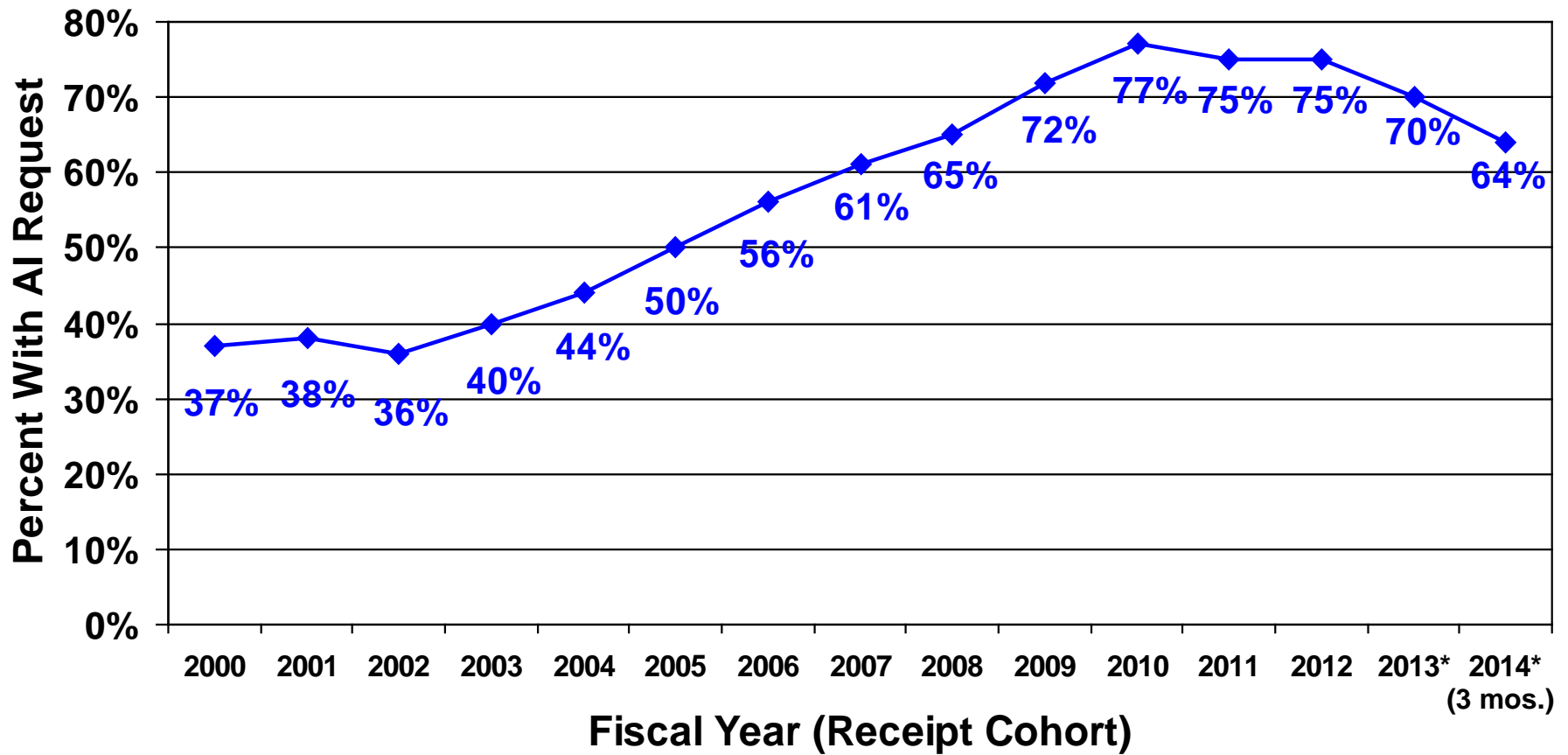
(October 1, 2013 thru December 31, 2013)

16. [Guideline for Industry and Food and Drug Administration Staff - Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate](#) (12/30/13)
17. [Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only - Guidance for Industry and Food and Drug Administration Staff](#) (11/25/13)
18. [Medical Device Development Tools - Draft Guidance for Industry, Tool Developers, and Food and Drug Administration Staff](#) (11/14/13)
19. [Design Considerations for Pivotal Clinical Investigations for Medical Devices - Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff](#) (11/07/13)
20. [Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff](#) (11/07/13)
21. [Guidance for Industry and Food and Drug Administration Staff - eCopy Program for Medical Device Submissions](#) (10/10/13)
22. [Investigational Device Exemptions \(IDEs\) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human \(FIH\) Studies - Guidance for Industry and Food and Drug Administration Staff](#) (10/01/13)

510(k)s

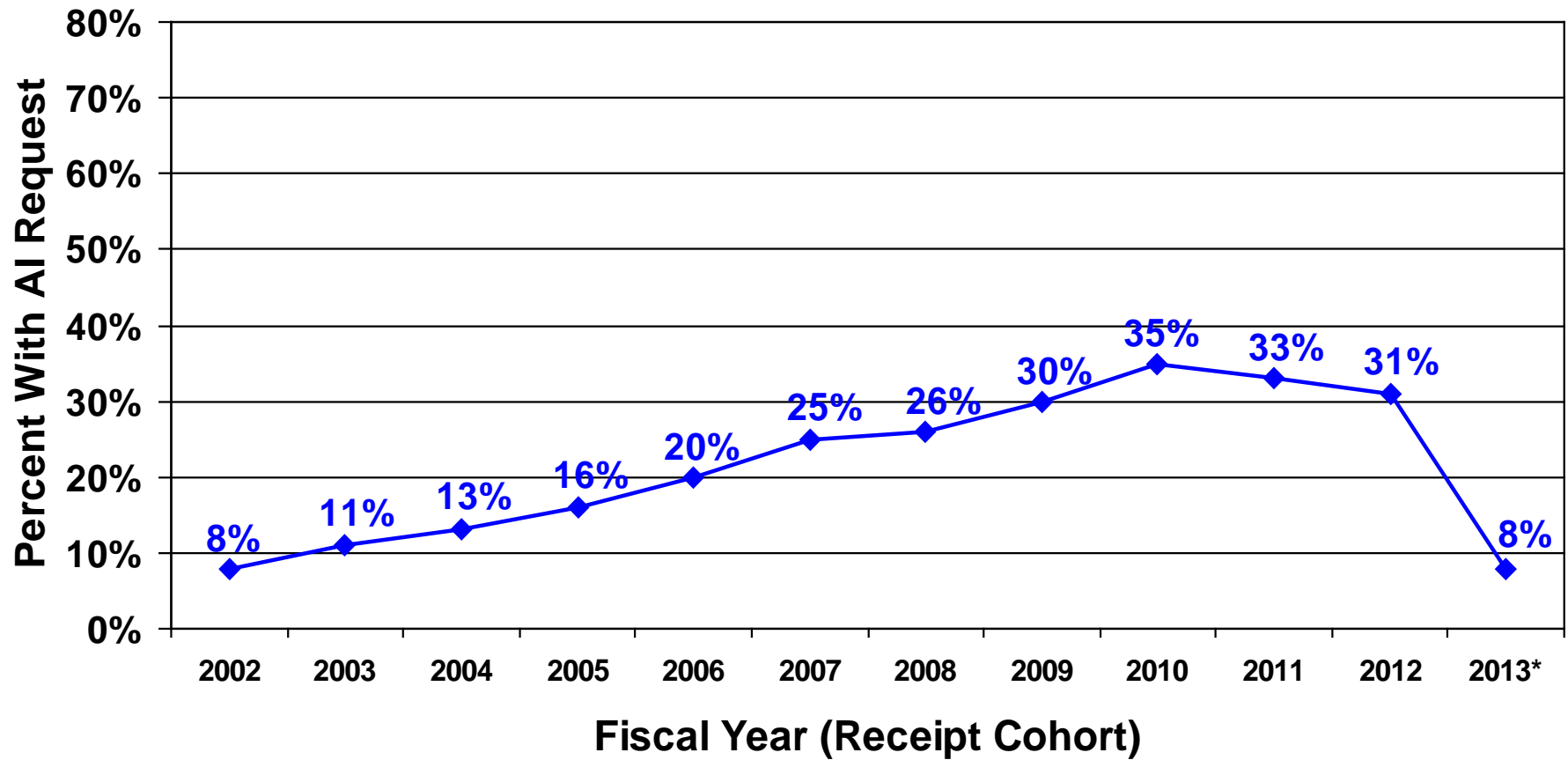


# Percent of 510(k)s With Additional Information (AI) Request on 1<sup>st</sup> FDA Review Cycle



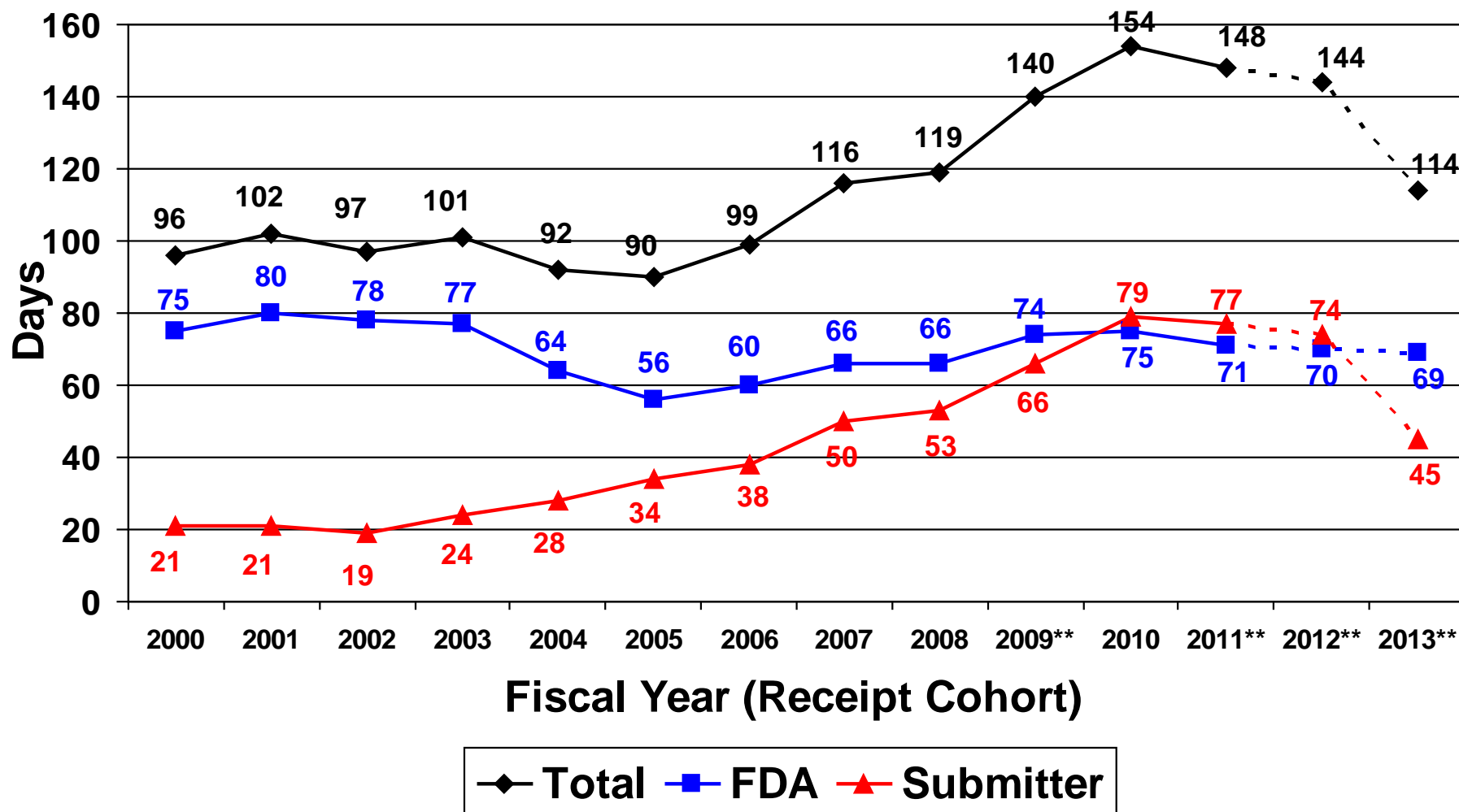
\*FY 2013 and FY 2014 data are based on the first substantive review cycle (i.e., excluding RTA cycles) for submissions accepted as of 12/31/2013

# Percent of 510(k)s With Additional Information (AI) Request on 2<sup>nd</sup> FDA Review Cycle



\*FY 2013 data are for 510(k)s accepted as of 09/30/2013

# Average Time to Decision: 510(k)s\* (Receipt Cohorts as of March 31, 2014)

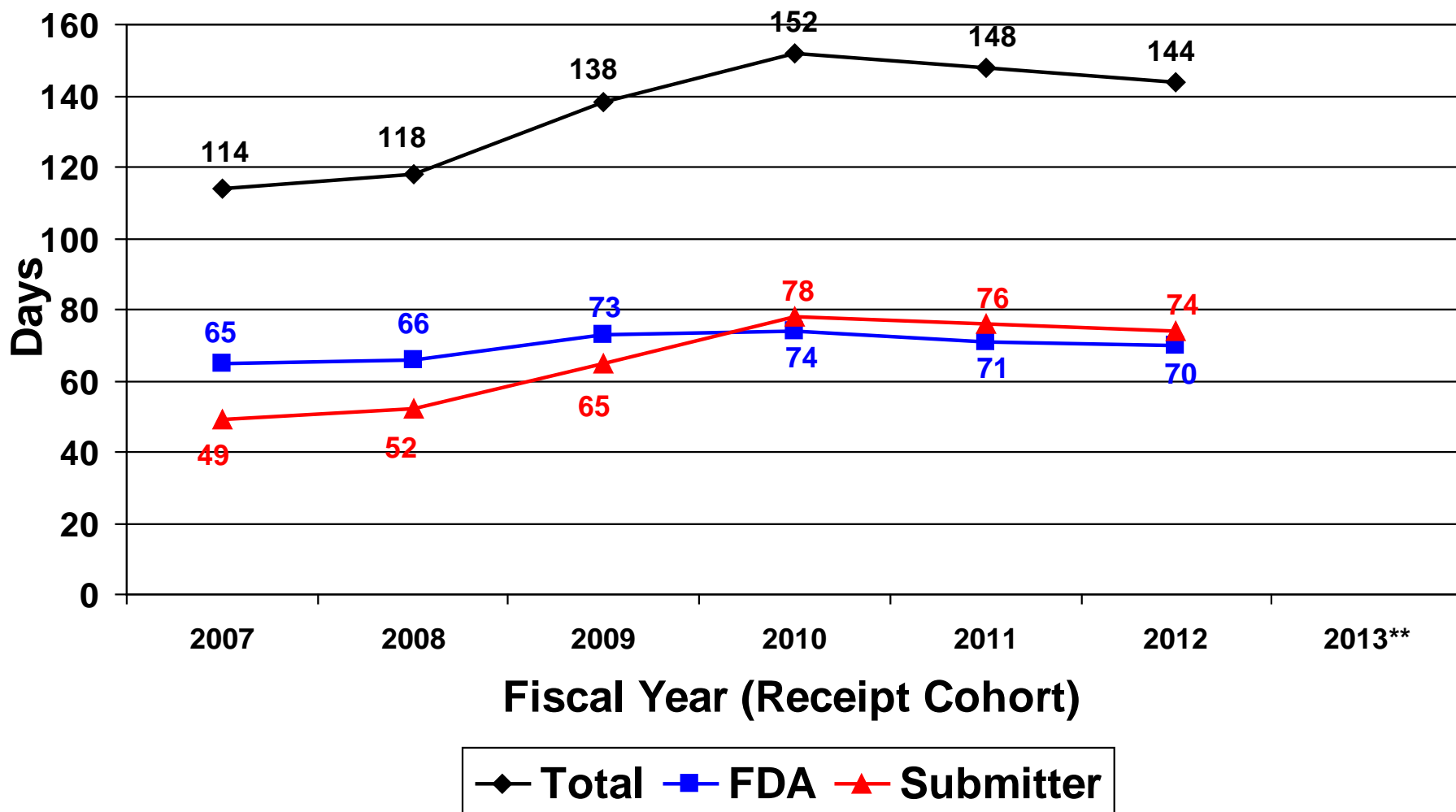


\*SE and NSE decisions only; times may not add to total due to rounding

\*\*Cohorts still open; FY 2012 cohort is 99.7% closed and FY 2013 cohort is 86.5% closed—average times will increase

# Average Time to Decision: 510(k)s\*

- Comparison of Receipt Cohorts When 99.7% Closed -

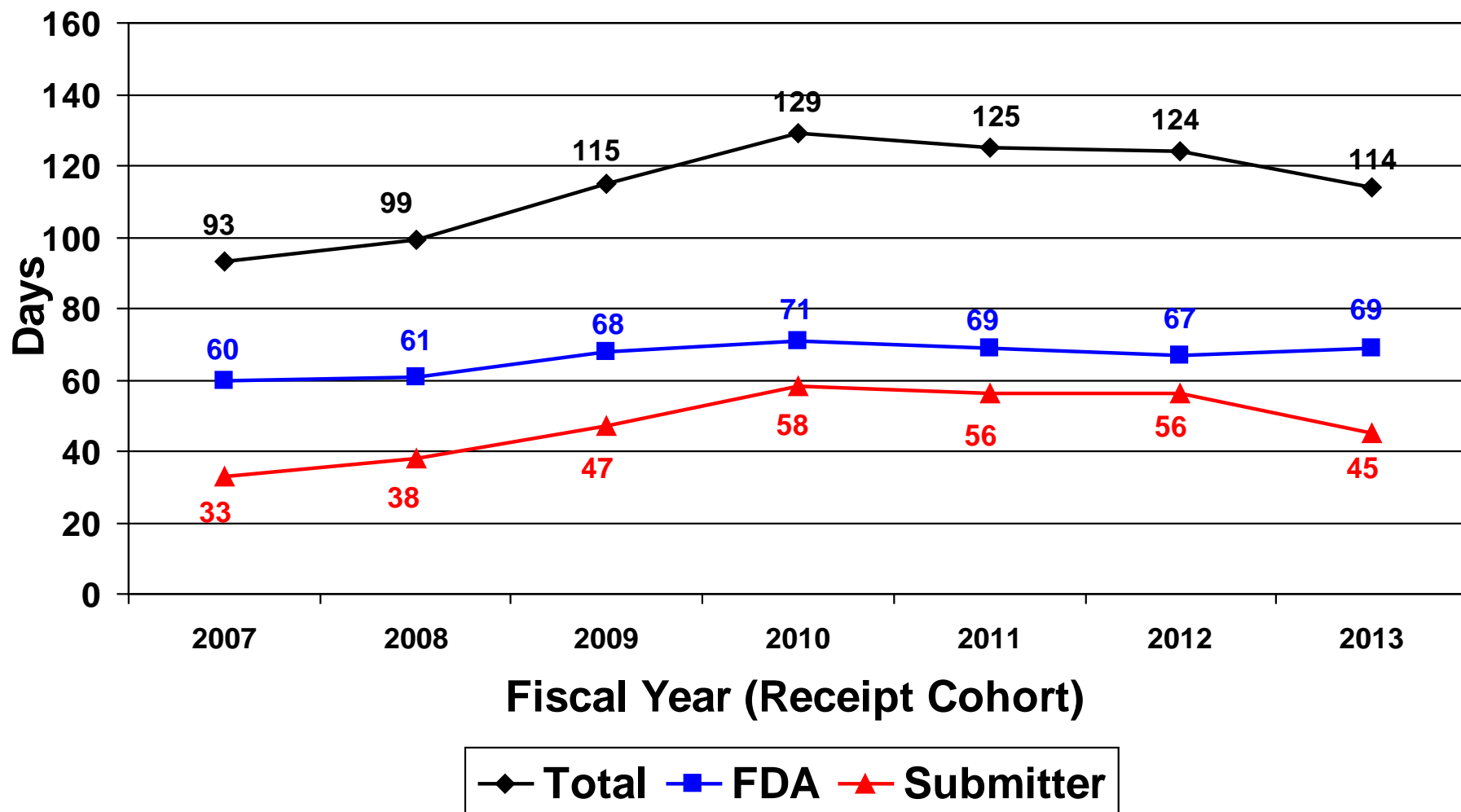


\*SE and NSE decisions only; times may not add to total due to rounding

\*\*FY 2013 cohort is not yet 99.7% closed (as of 03/31/2014)

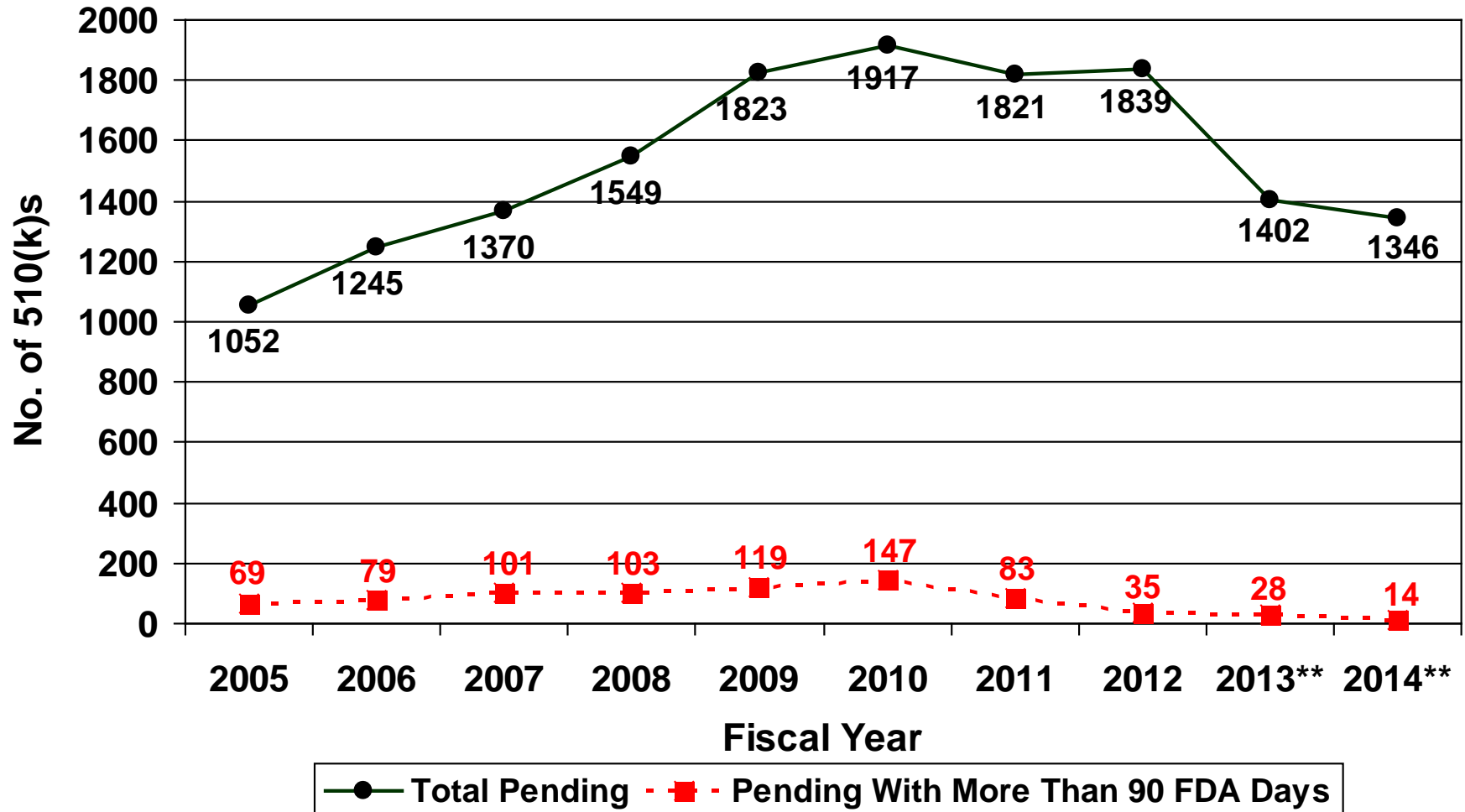
# Average Time to Decision: 510(k)s\*

- Comparison of Receipt Cohorts When 86.5% Closed -



\*SE and NSE decisions only; times may not add to total due to rounding

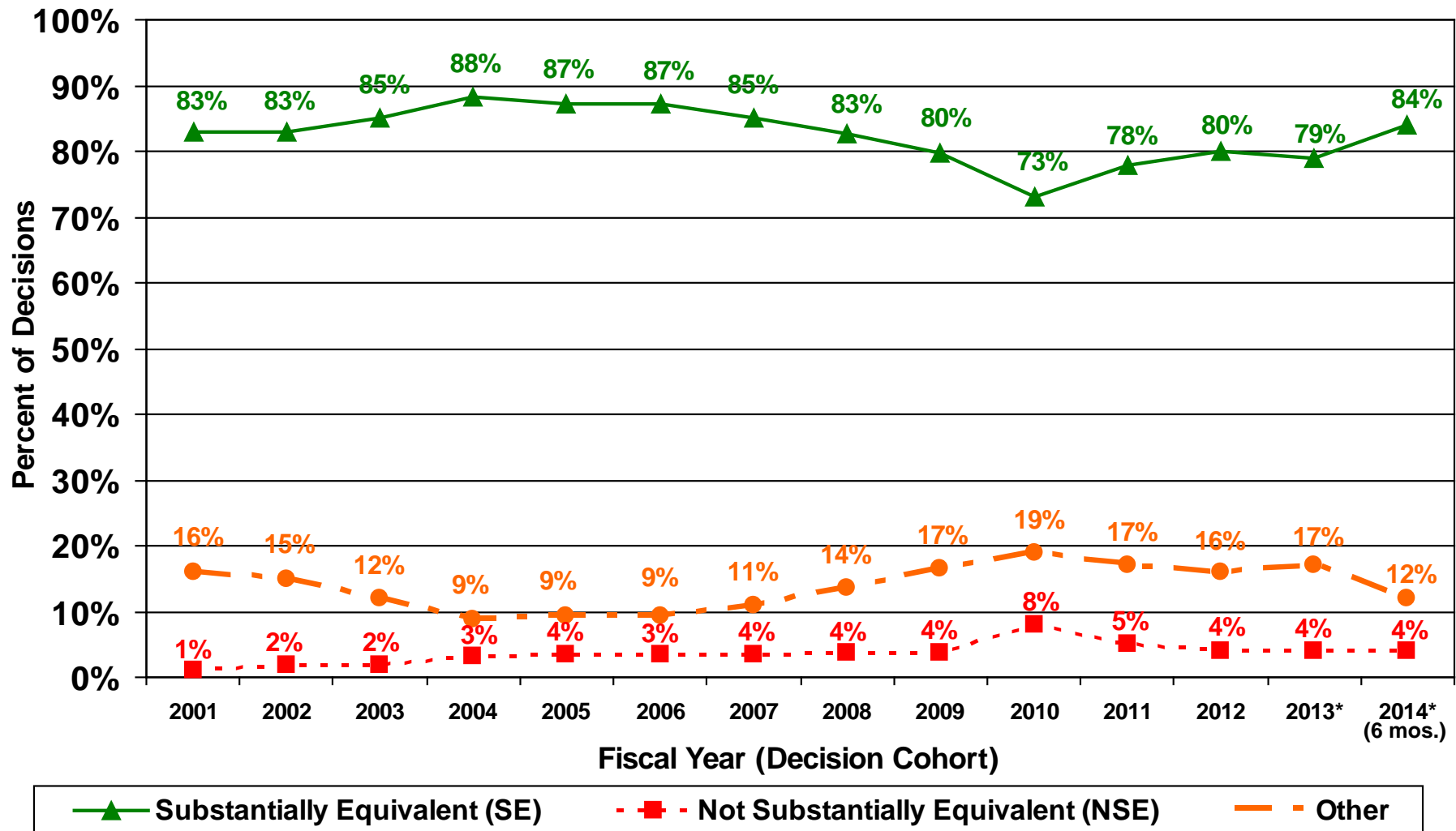
# 510(k)s Pending\* at End of Year



\*Under review or on hold

\*\*Excludes FY 2013 and FY 2014 receipts that have not been accepted for substantive review; FY 2014 is as of 03/31/2014

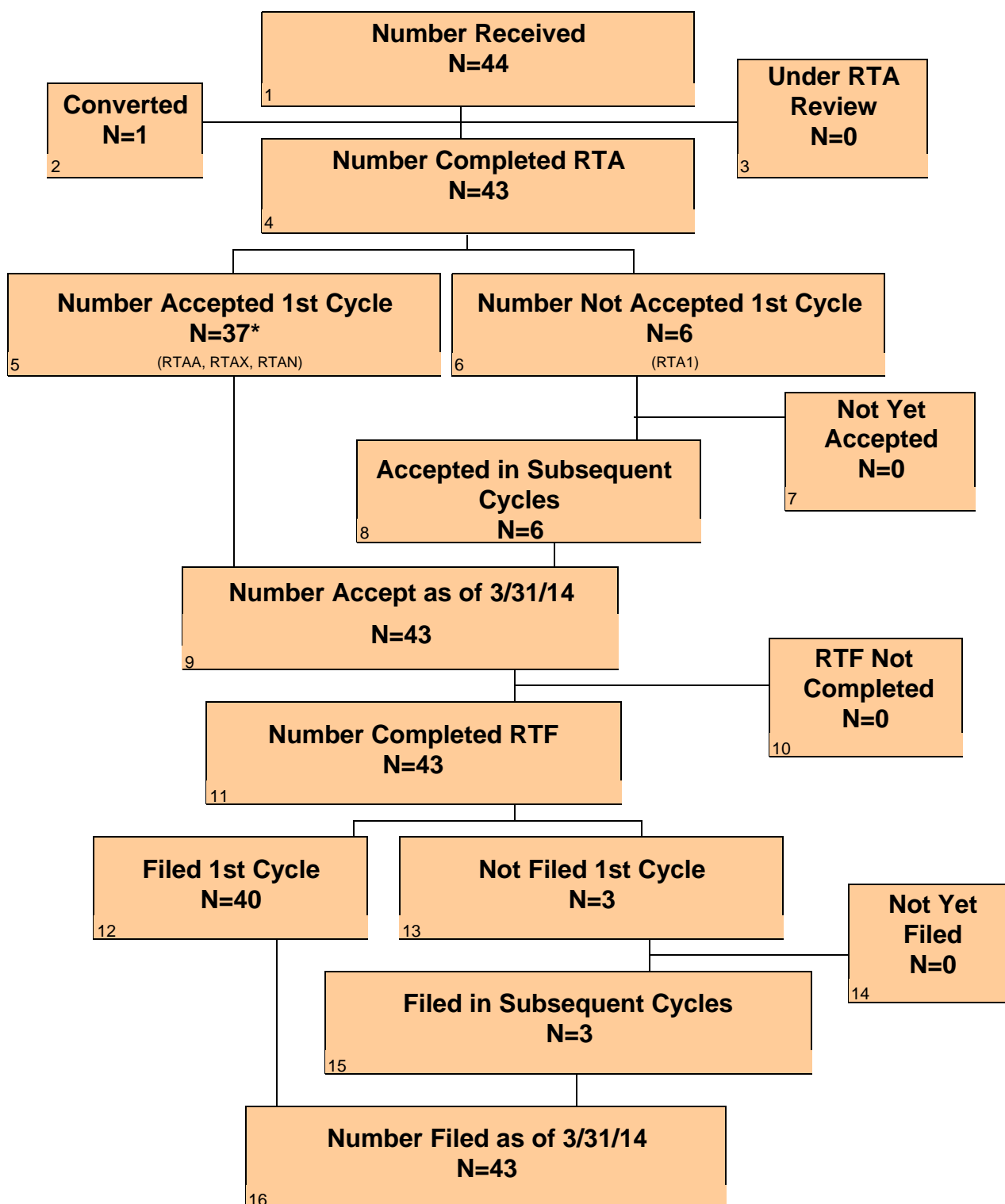
# Percent of 510(k)s Determined to be Substantially Equivalent (SE)



\*Excludes final decisions made on FY 2013 and FY 2014 receipts that were not accepted for substantive review as of 03/31/2014

# CDRH PMA Original and Panel Track Supplements - FY2013 As of 3/31/14

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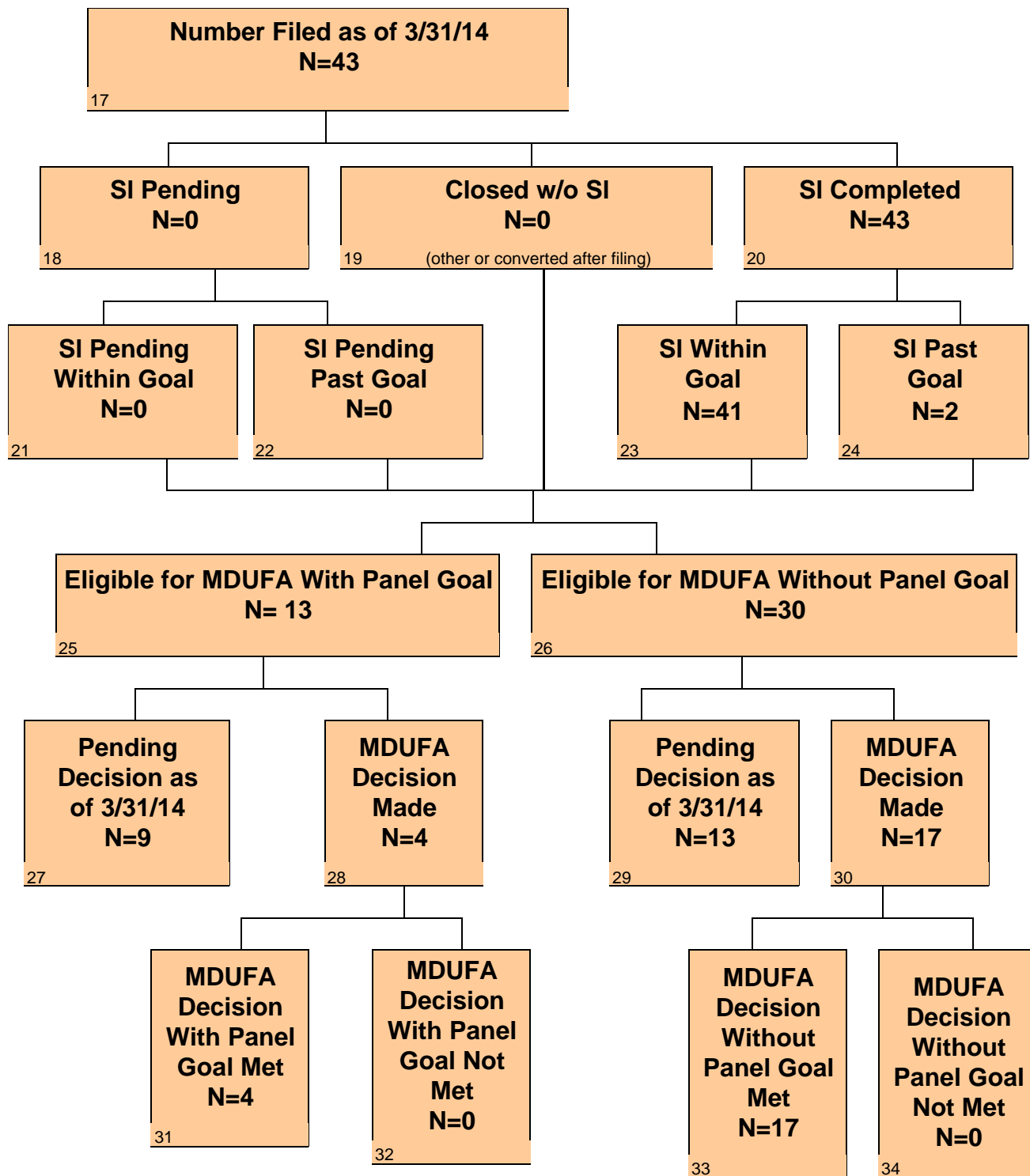


\* Includes 10 accepted 1<sup>st</sup> Quarter, prior to implementation of RTA refusal

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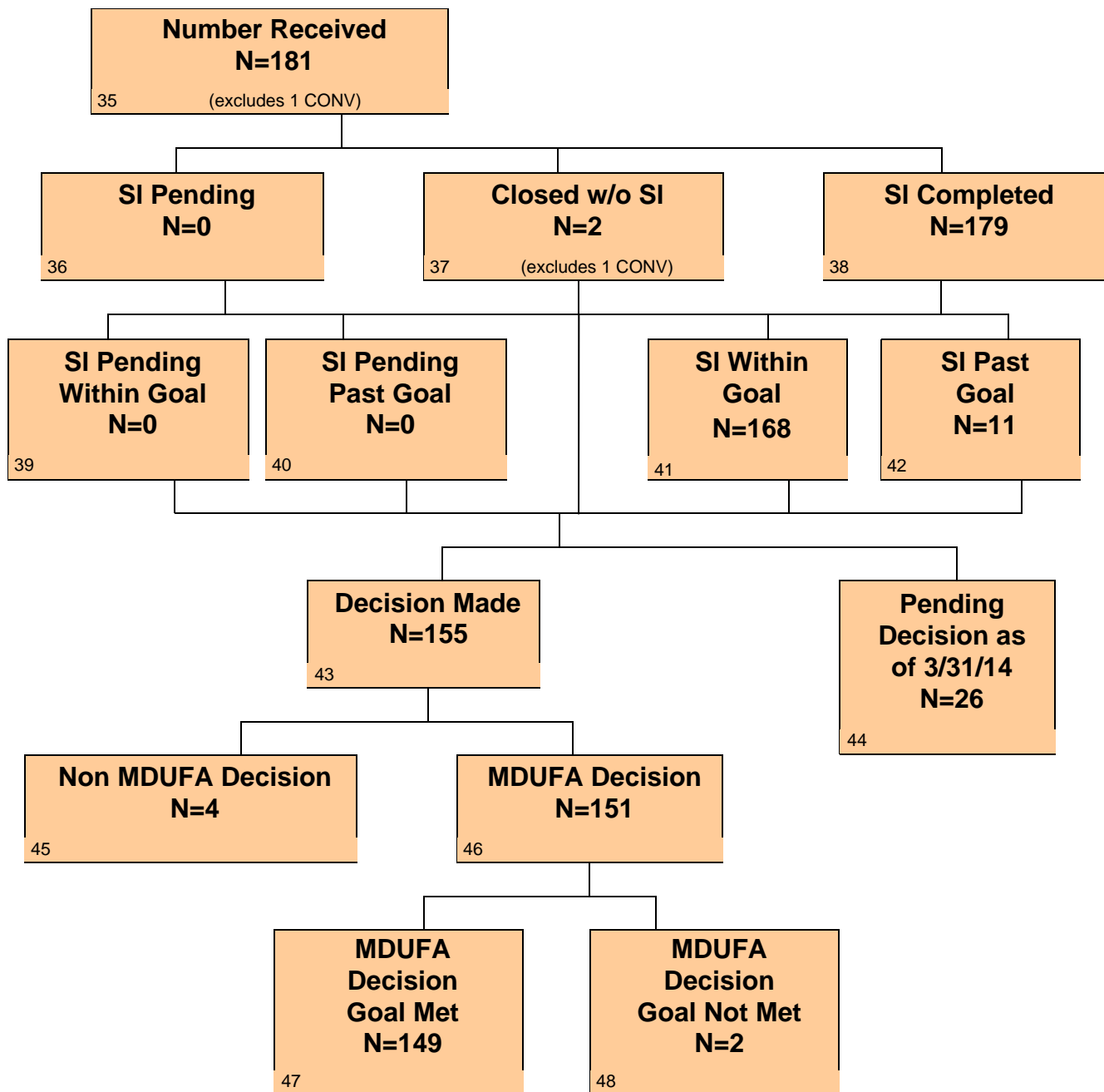


# CDRH PMA Original and Panel Track Supplements- FY2013 As of 3/31/14 Con't



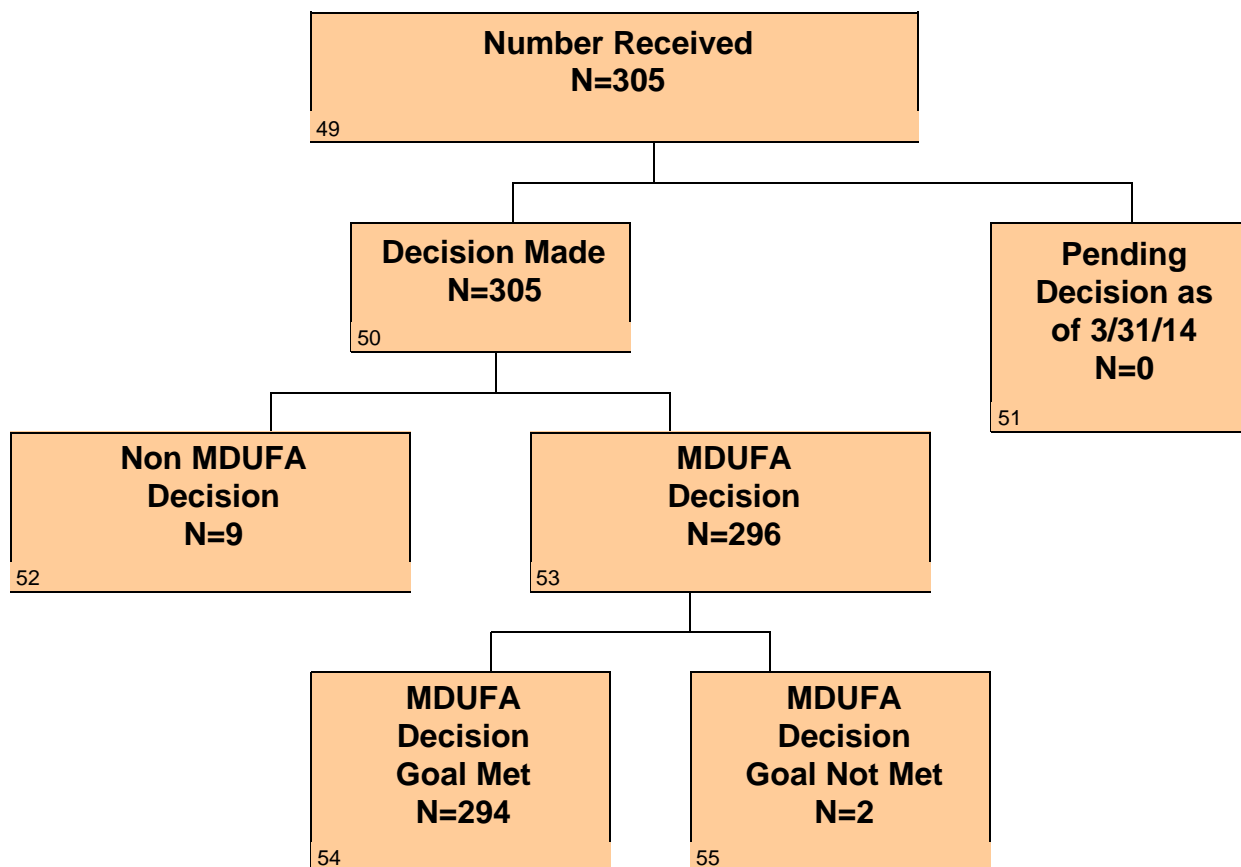
# CDRH PMA 180 Day Supplements - FY2013 As of 3/31/14

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# CDRH PMA Real Time Supplements - FY2013 As of 3/31/14

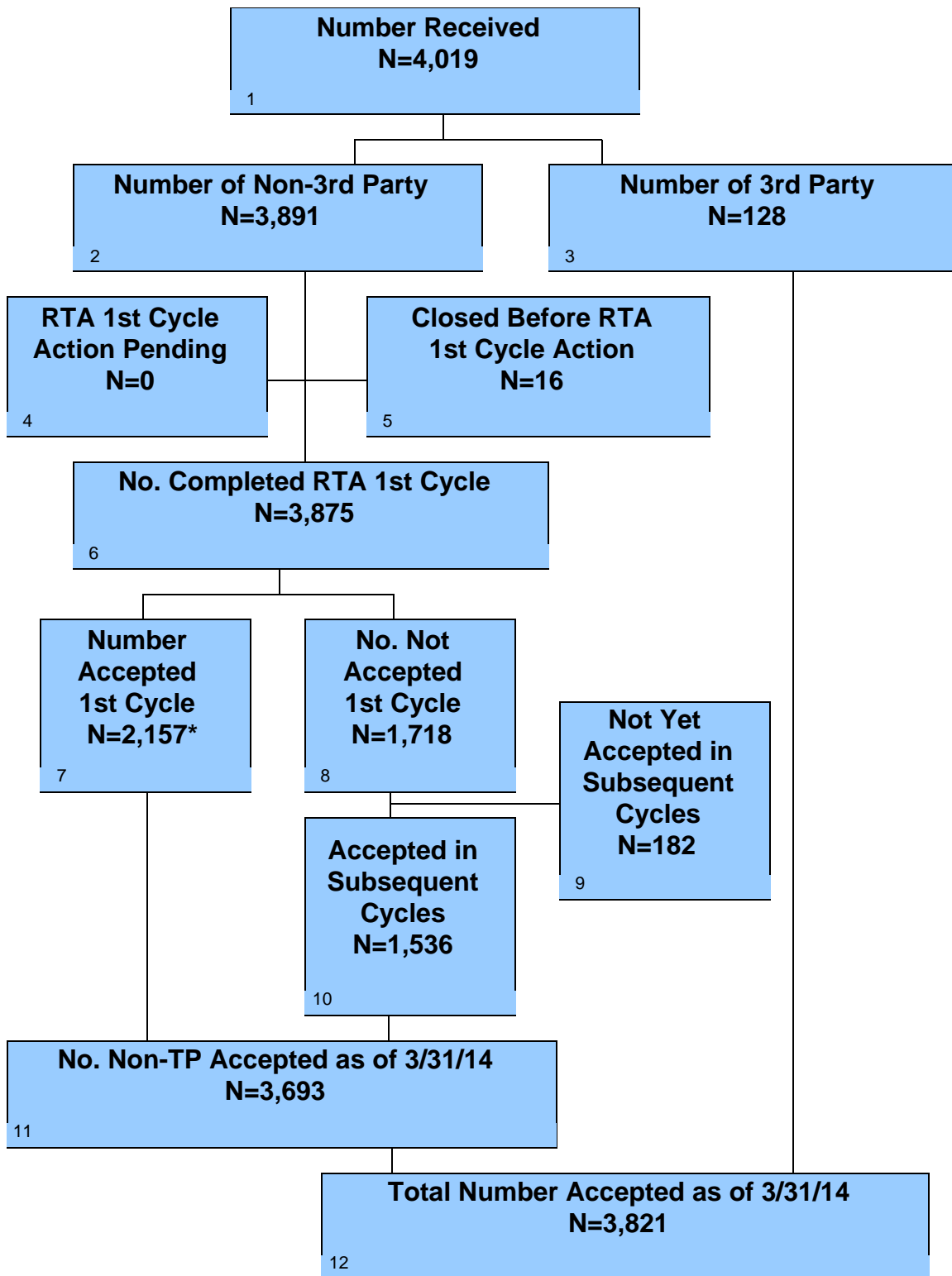
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# CDRH 510(k)s – FY2013

## As of 3/31/14

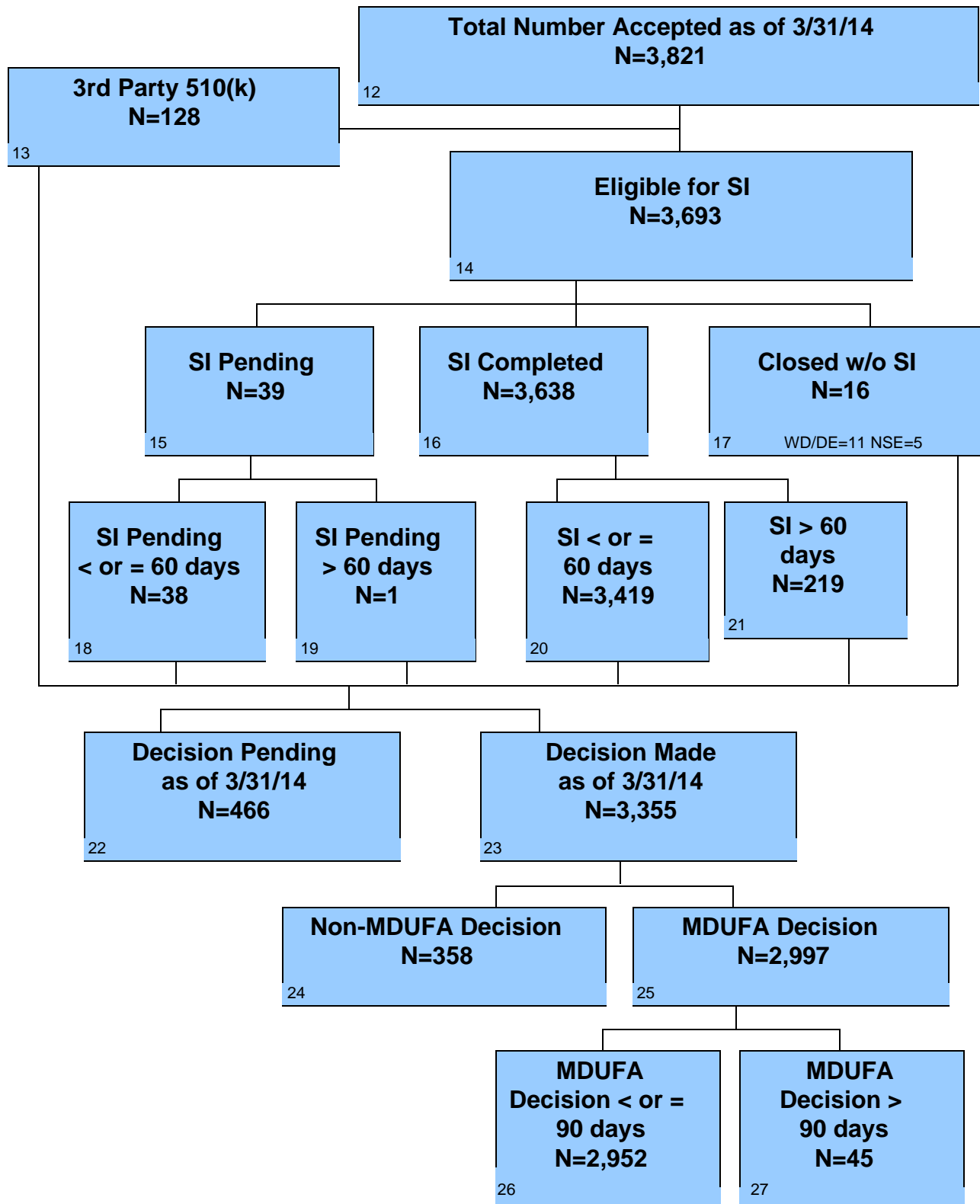
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\*Includes 919 accepted 1<sup>st</sup> Quarter, prior to implementation of RTA refusal

# CDRH 510(k)s – FY2013

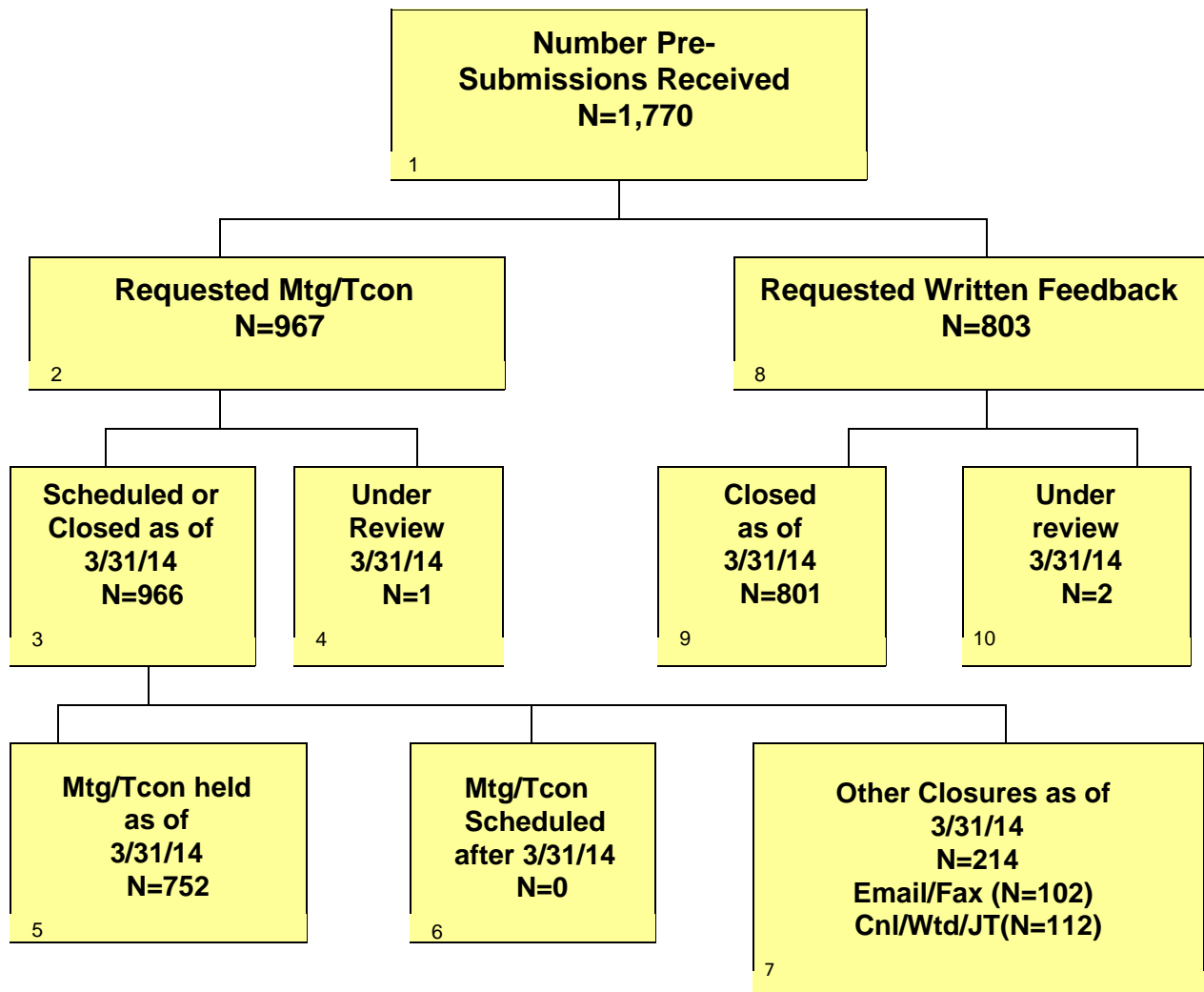
## As of 3/31/14 Con't



# CDRH Pre-Submissions – FY2013

## As of 3/31/14

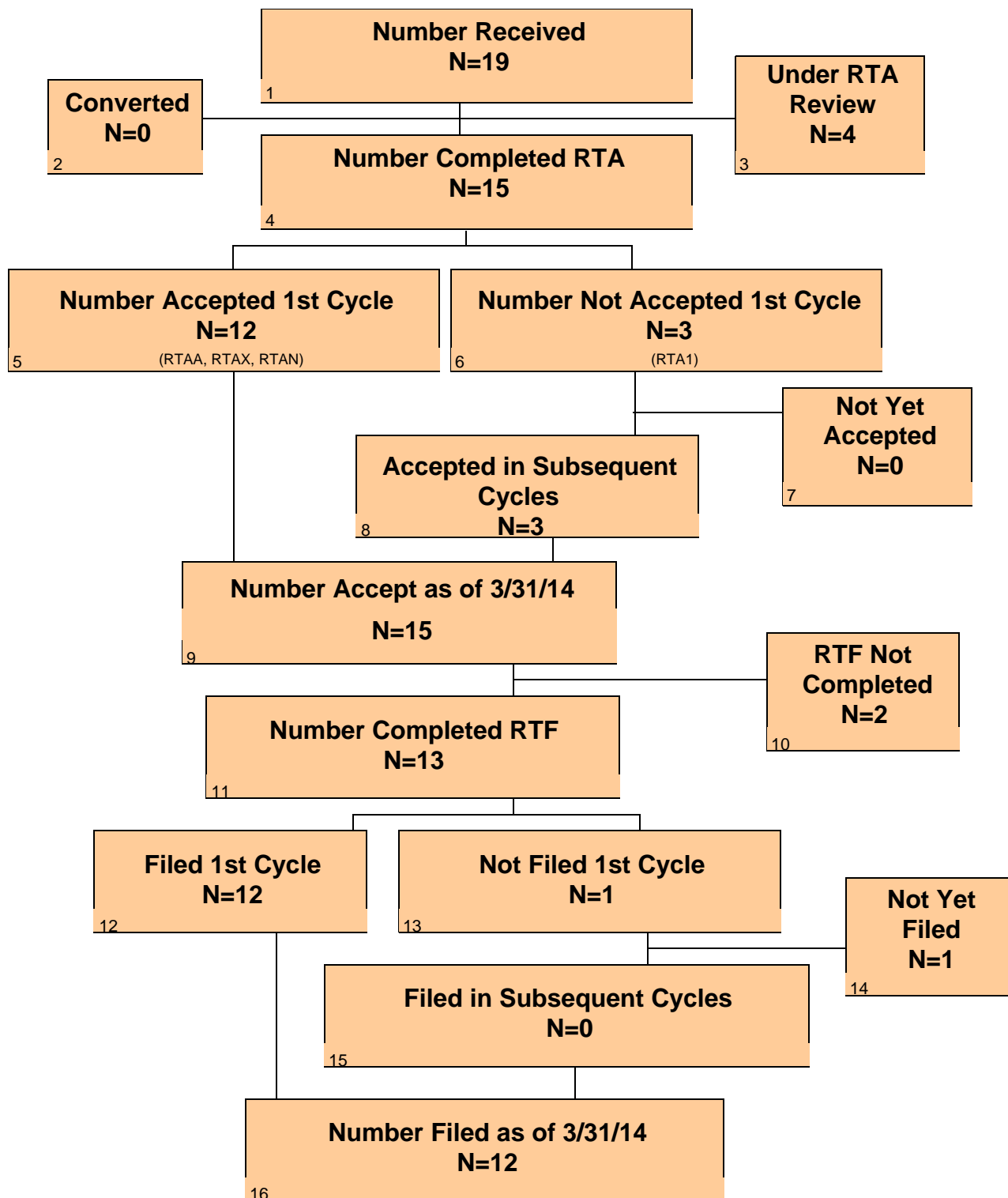
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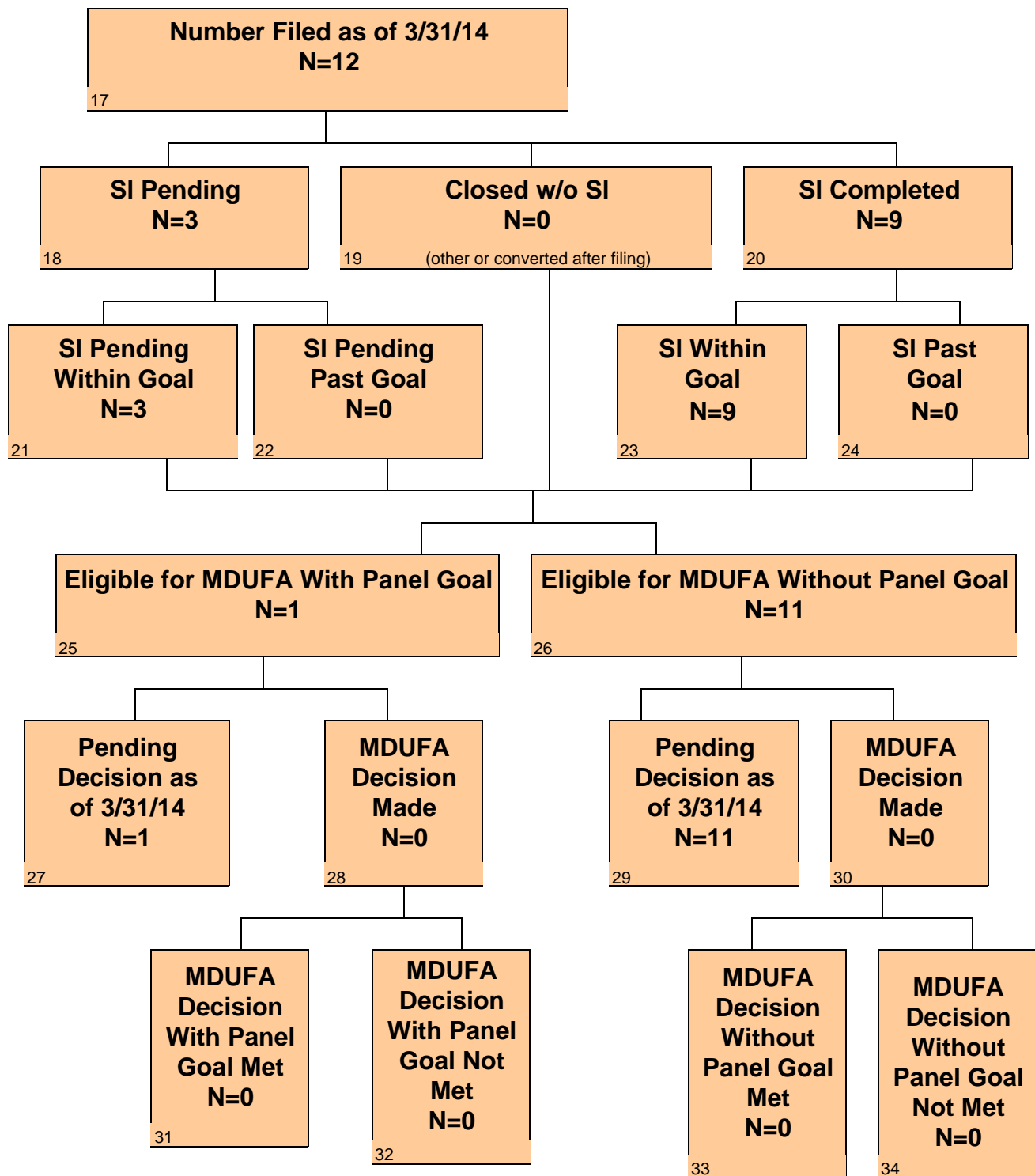
Cnl = Meeting/Tcon cancelled; Wtd = Submission withdrawn; JT = Jurisdiction transferred or pending transfer

# CDRH PMA Original and Panel Track Supplements - FY2014 As of 3/31/14

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# CDRH PMA Original and Panel Track Supplements - FY2014 As of 3/31/14 Con't

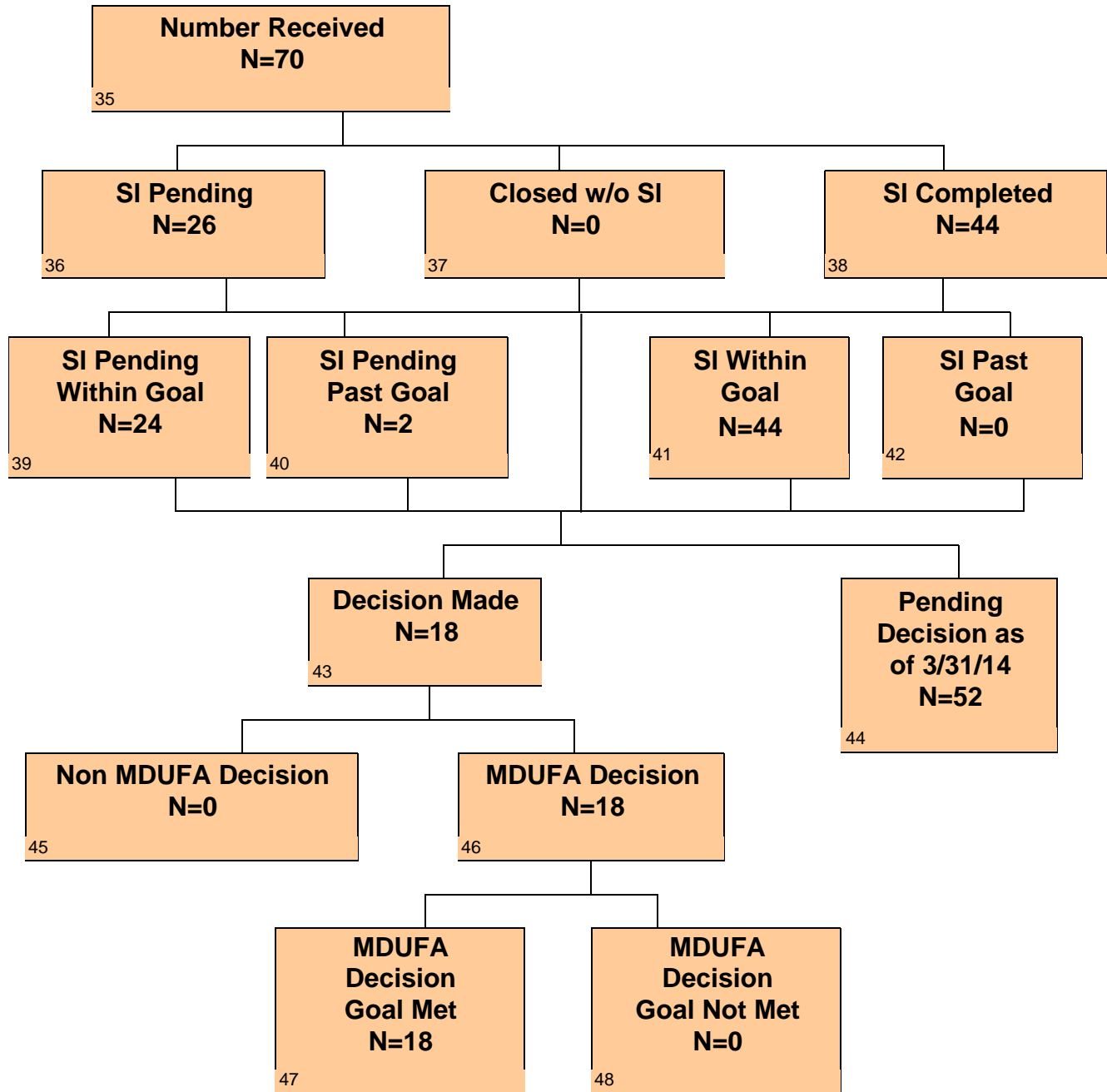




# CDRH PMA 180 Day Supplements - FY2014

## As of 3/31/14

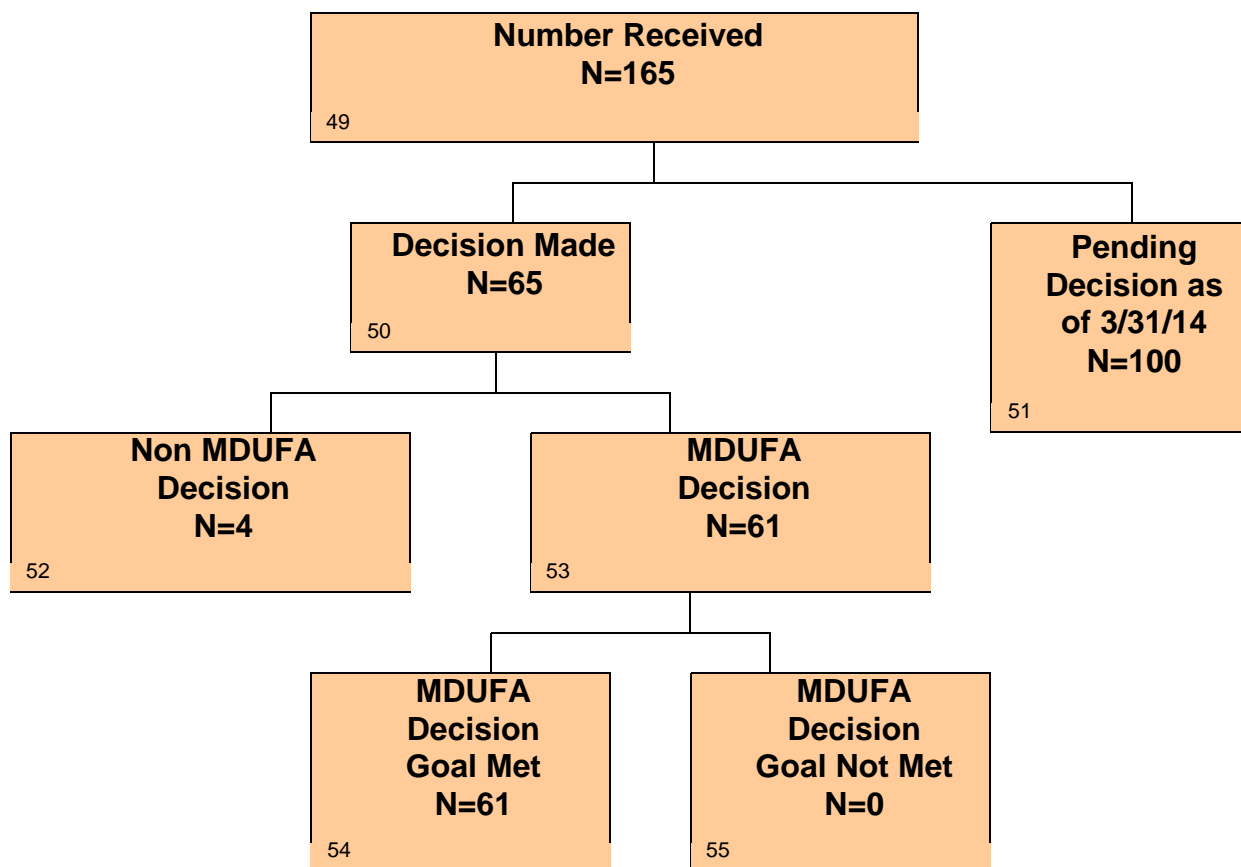
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# CDRH PMA Real Time Supplements - FY2014

## As of 3/31/14

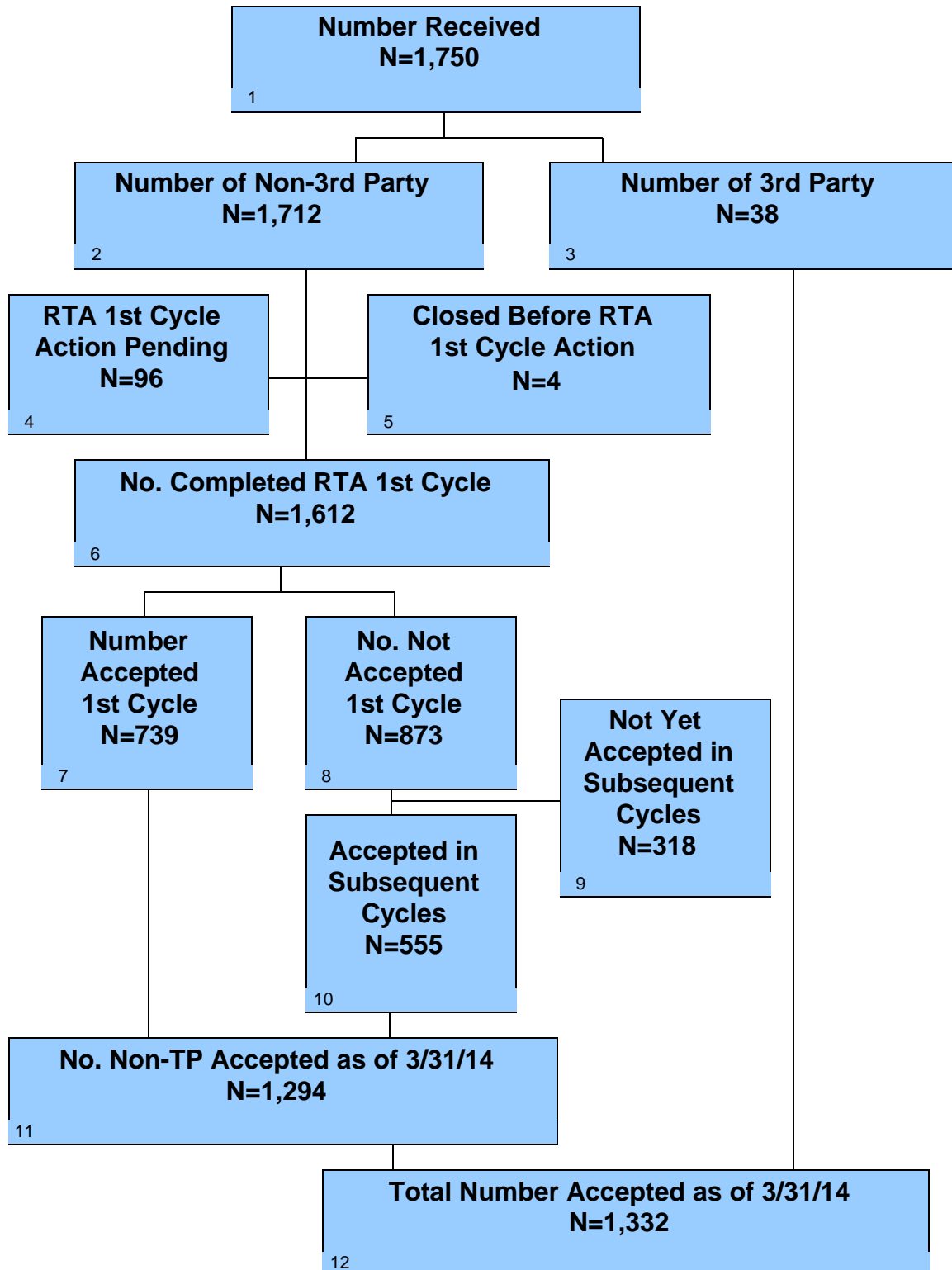
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# CDRH 510(k)s – FY2014

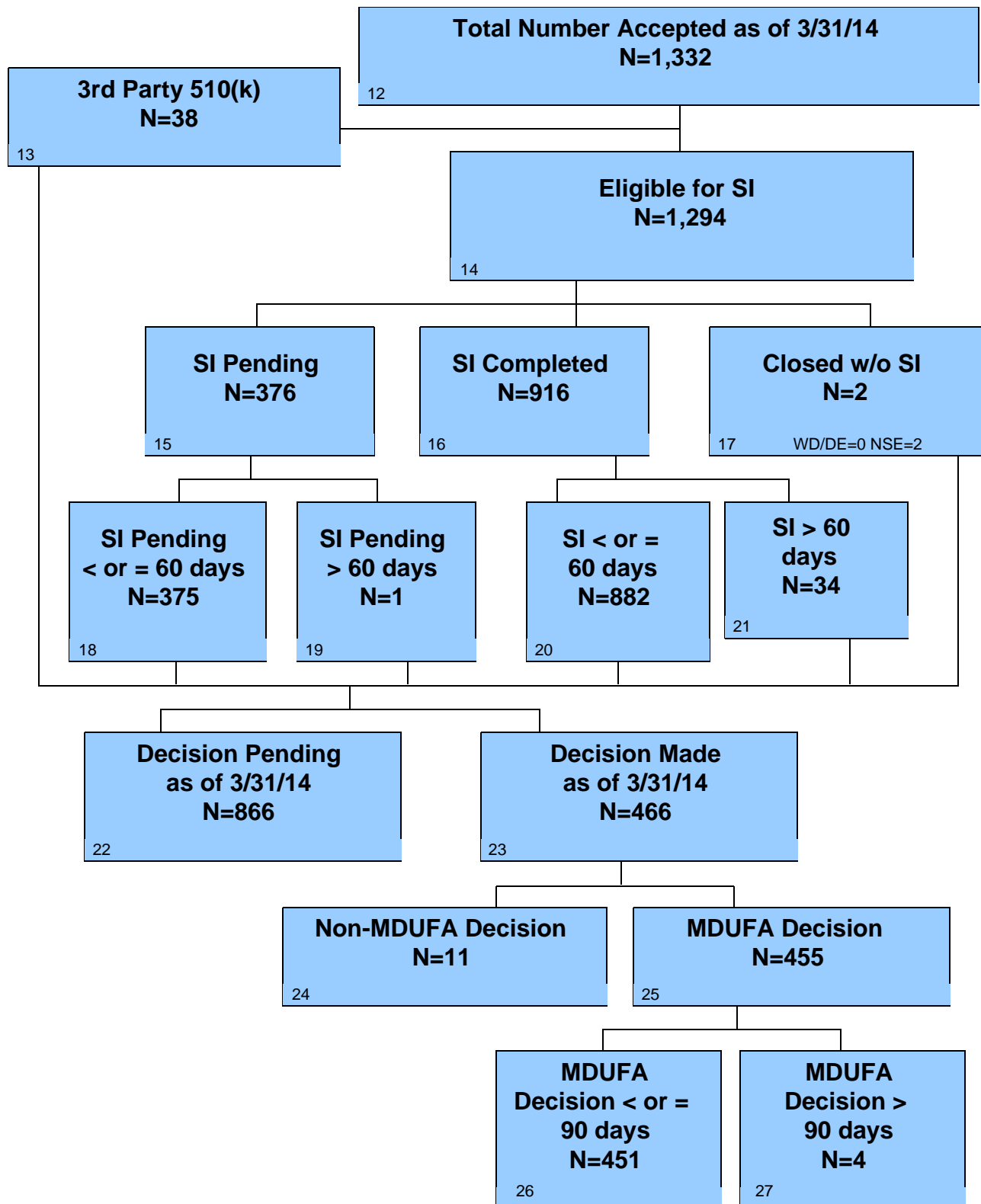
## As of 3/31/14

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# CDRH 510(k)s – FY2014

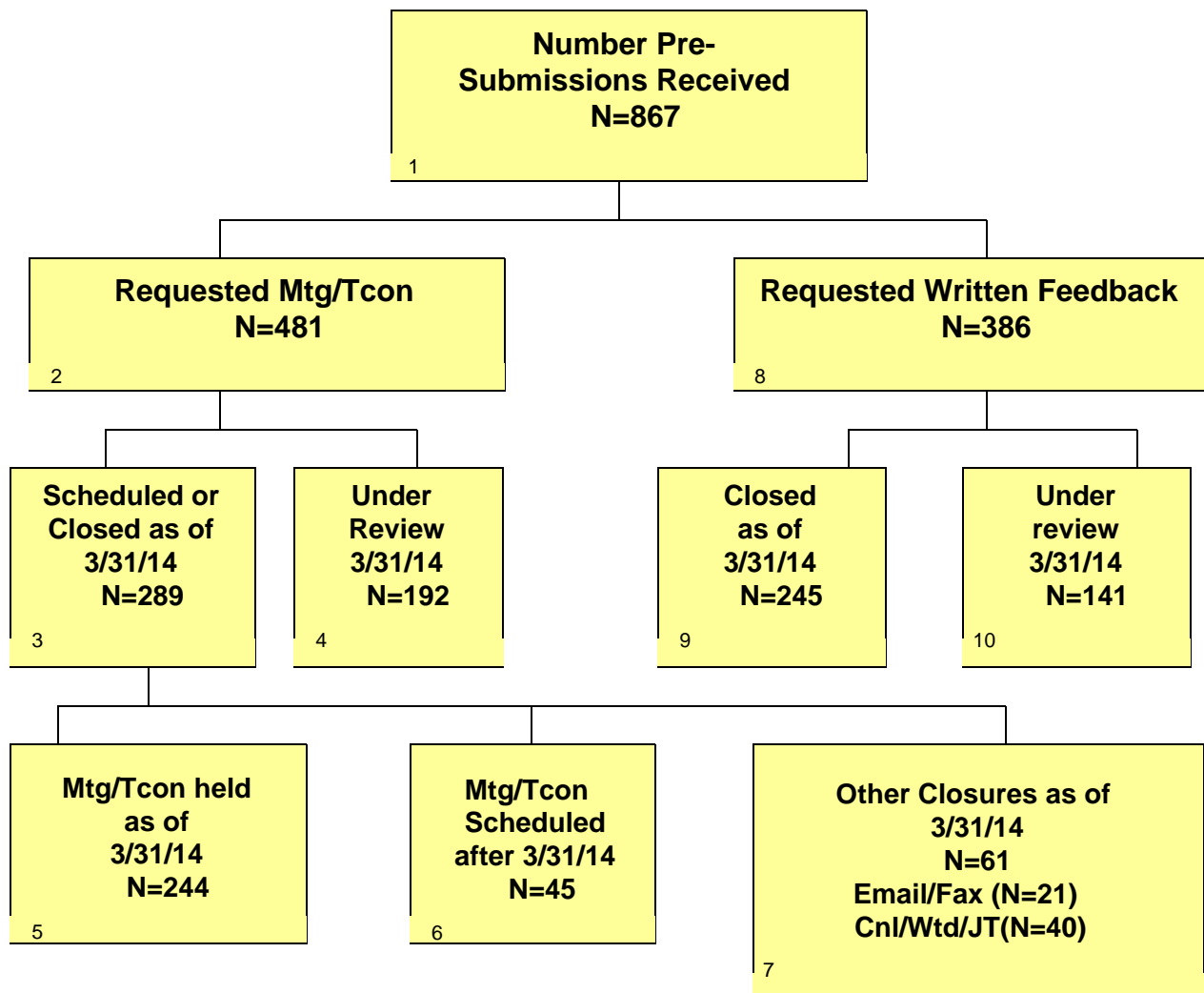
## As of 3/31/14 Con't



# CDRH Pre-Submissions – FY2014

## As of 3/31/14

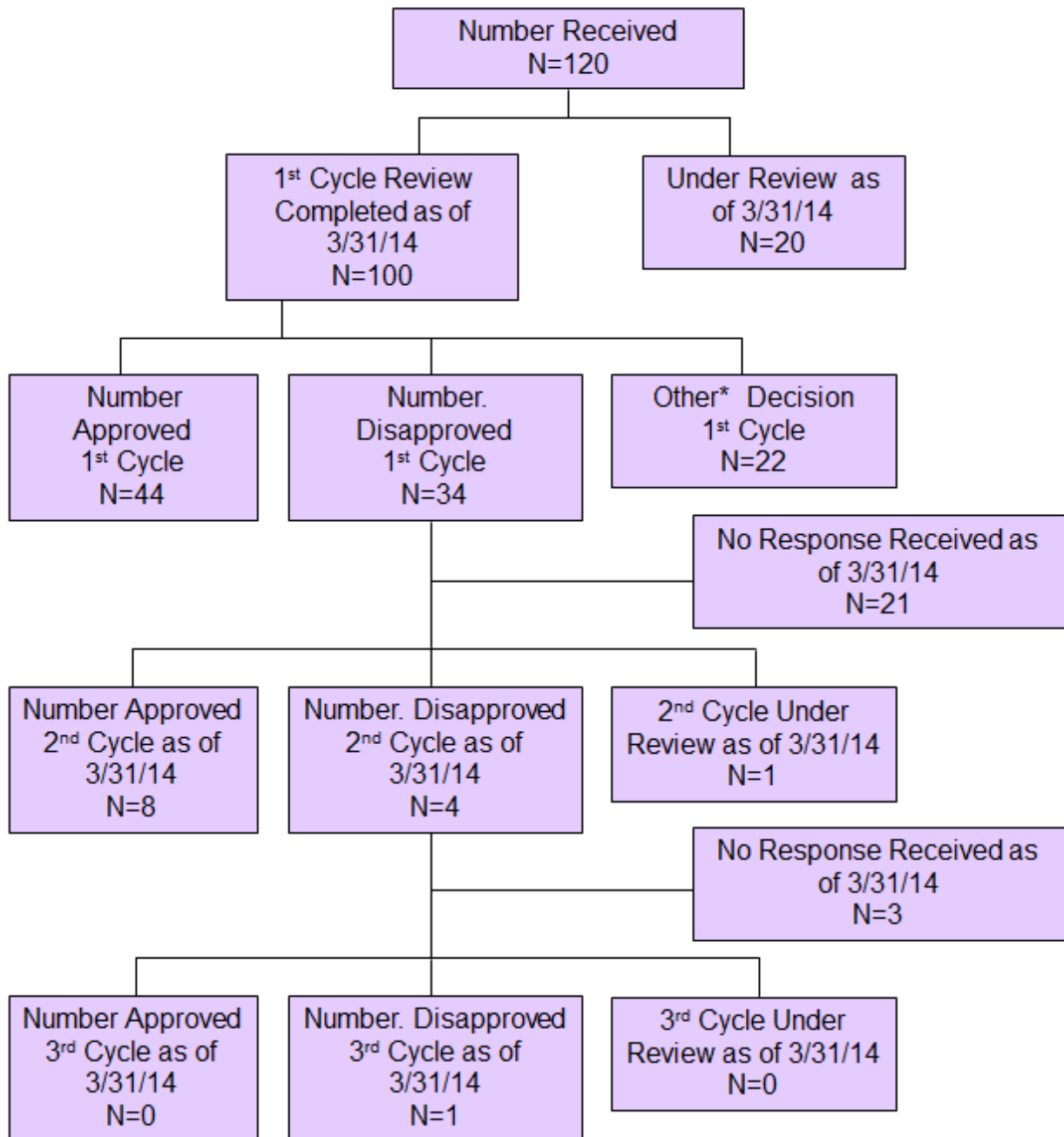
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Cnl = Meeting/Tcon cancelled; Wtd = Submission withdrawn; JT = Jurisdiction transferred or pending transfer

# CDRH IDEs - FY2014

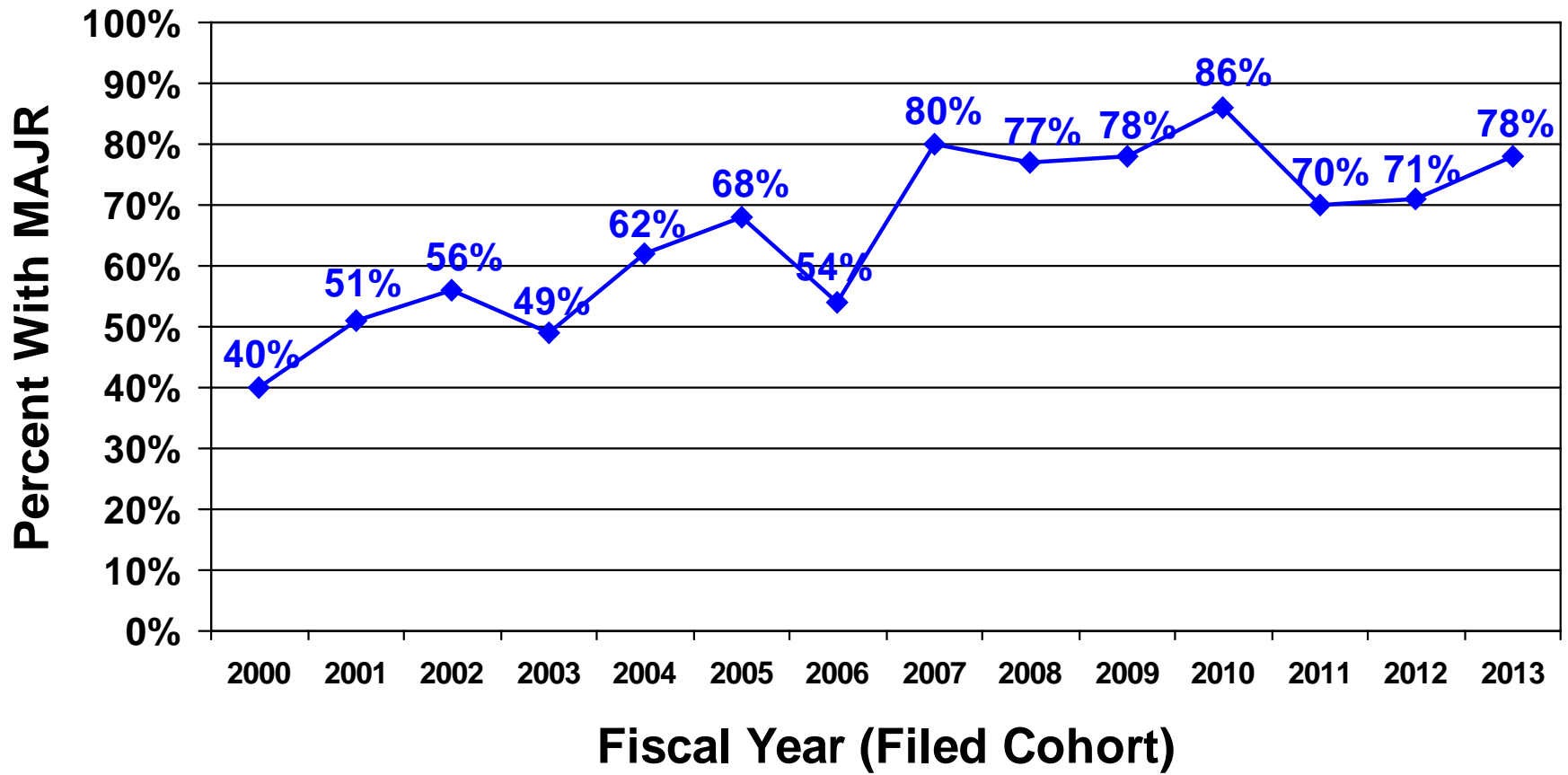
## As of 3/31/14



\* Other decisions include product jurisdiction transferred (n=2), nonsignificant risk device (n=4), RTA (n=2), or withdrawn (n=14)

PMA<sub>s</sub>

# Percent of PMAs With Major Deficiency Letter (MAJR) on 1<sup>st</sup> FDA Review Cycle\*

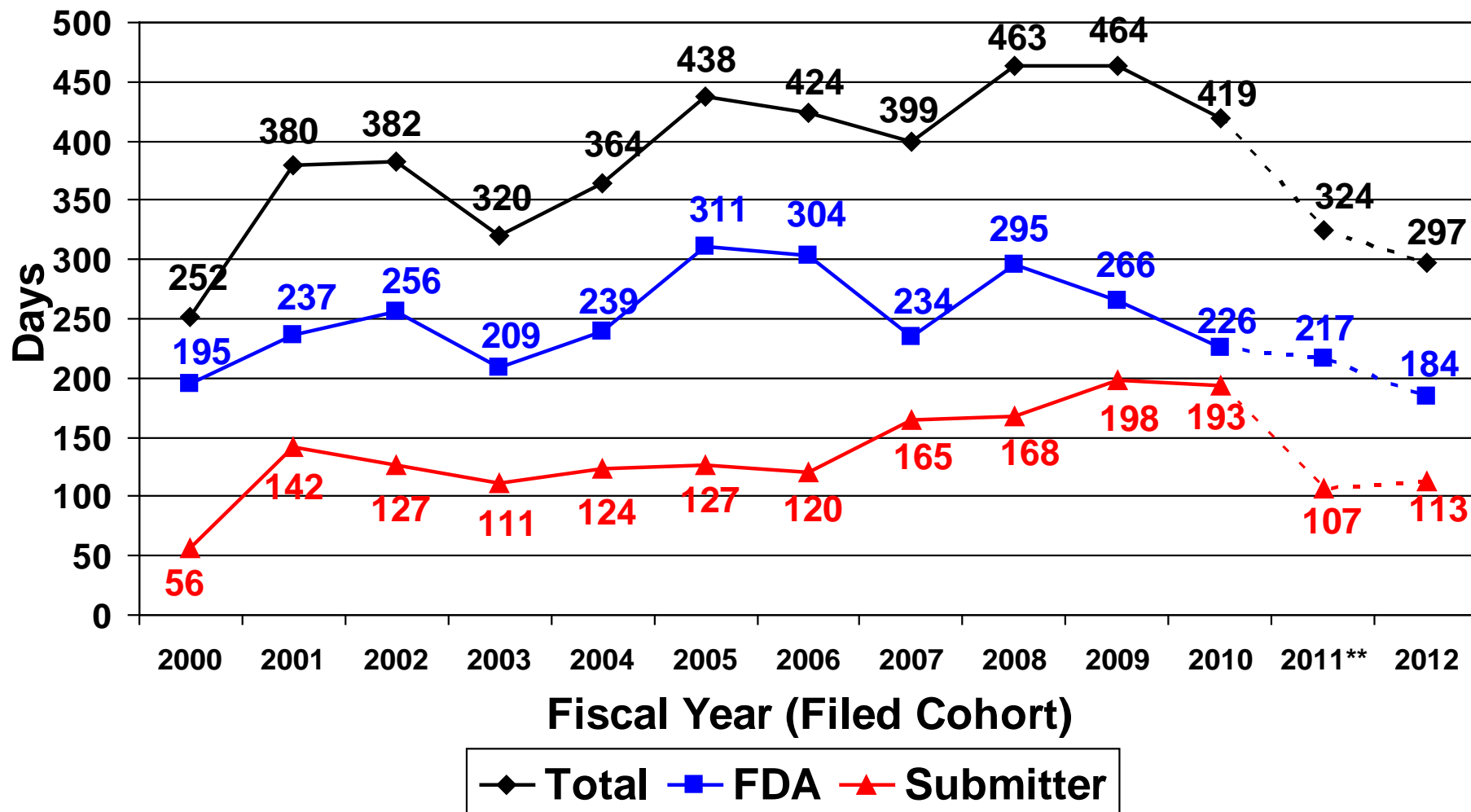


\*Includes filed original PMAs; FY 2013 excludes 1 filed PMA for which the 1<sup>st</sup> cycle was incomplete as of 03/31/2014.



# Average Time to MDUFA Decision: PMAs\*

(Filed Cohorts as of March 31, 2014)

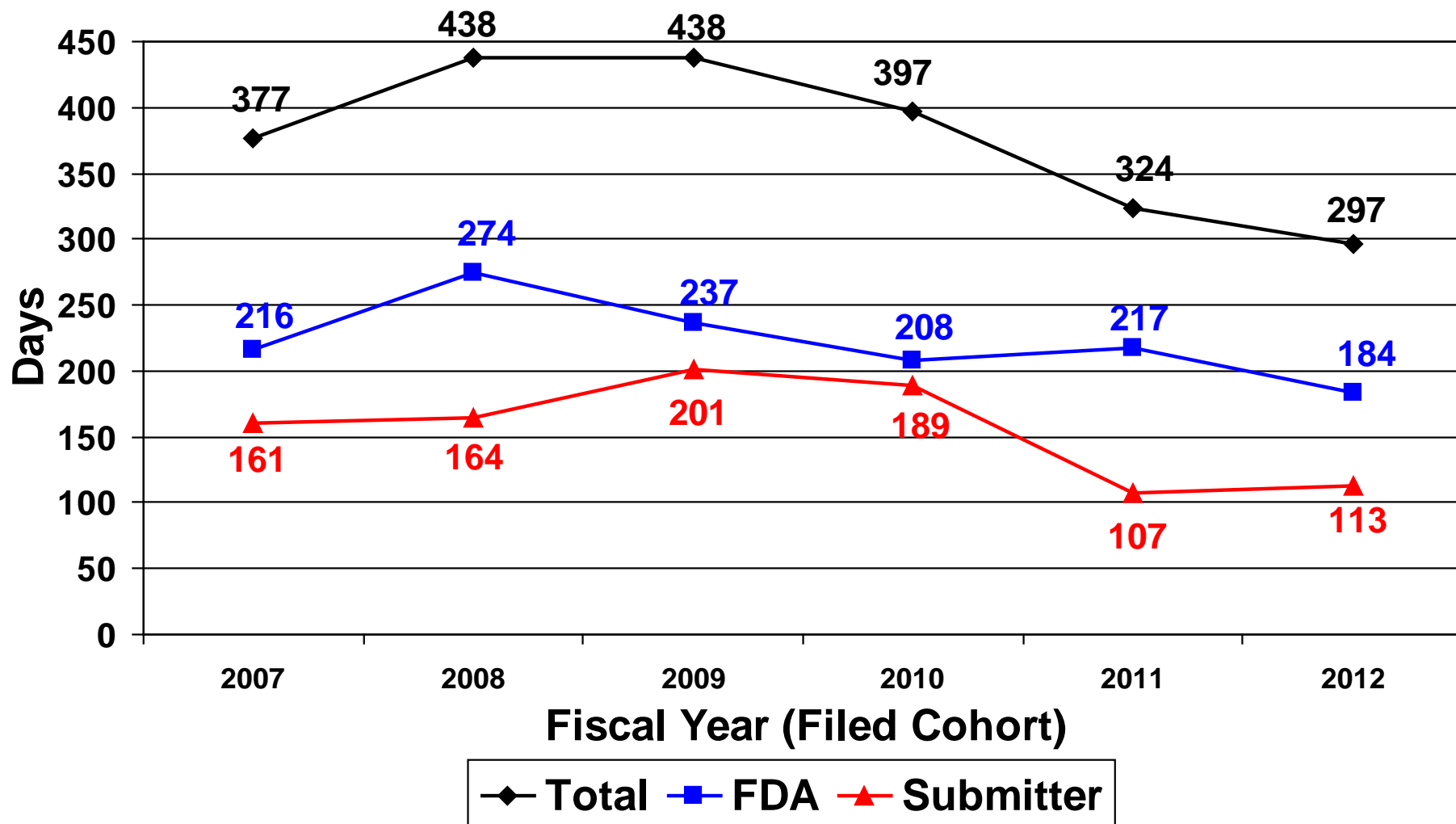


\*Includes all filed original PMAs; times may not add to total due to rounding

\*\*Cohort still open, average times will increase; percent of cohort with MDUFA decision:  
FY11 = 98% (42/43)

# Average Time to MDUFA Decision: PMAs\*

- Comparison of Filed Cohorts When Approx. 98% Closed\*\* -

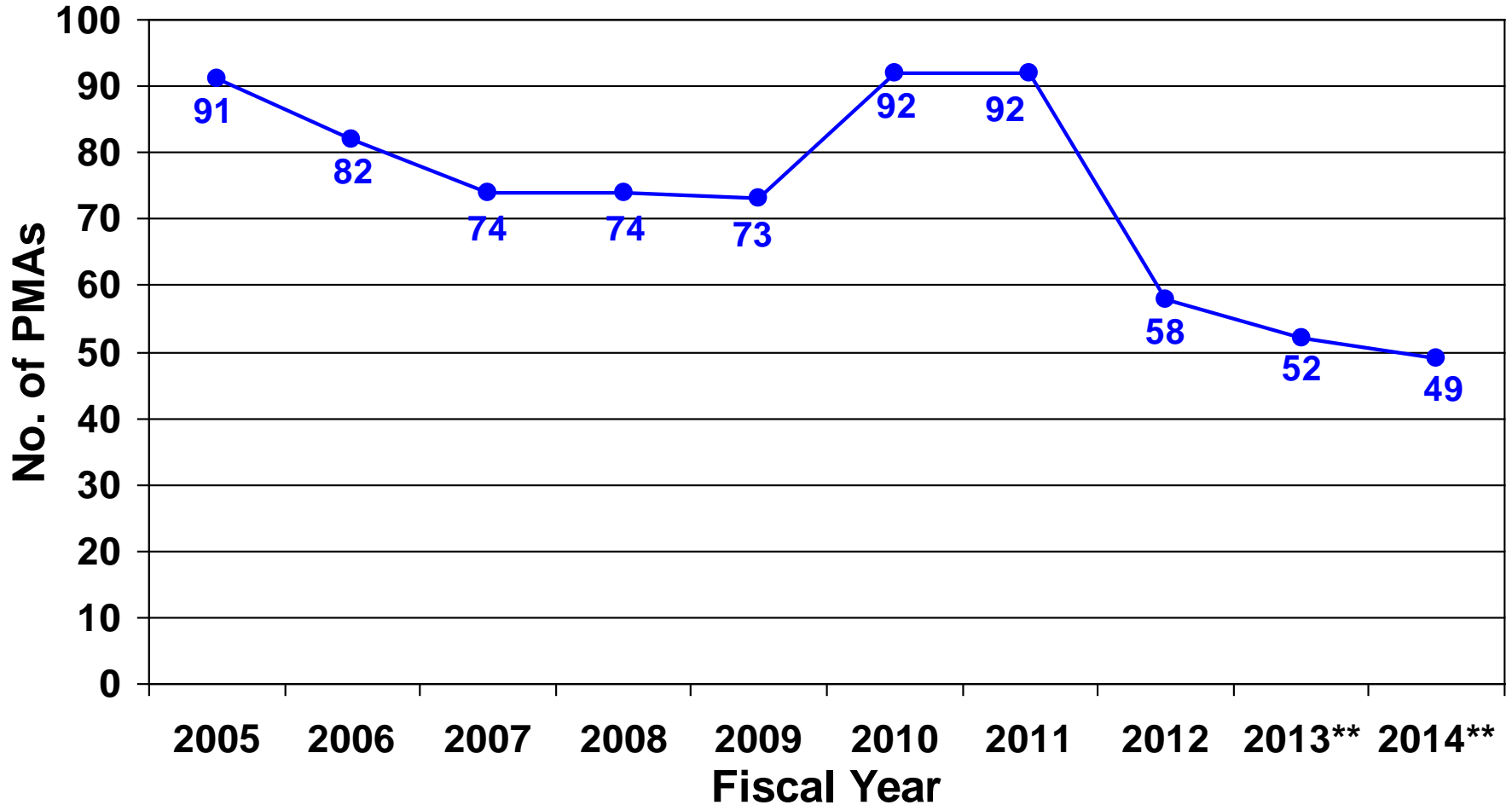


\*Includes all filed original PMAs; times may not add to total due to rounding

\*\*Proportion of cohort closed (MDUFA decision):

FY07 = 34/35; FY08 = 29/30; FY09 = 31/32; FY10 = 42/43; FY11 = 42/43; FY12 = 24/24

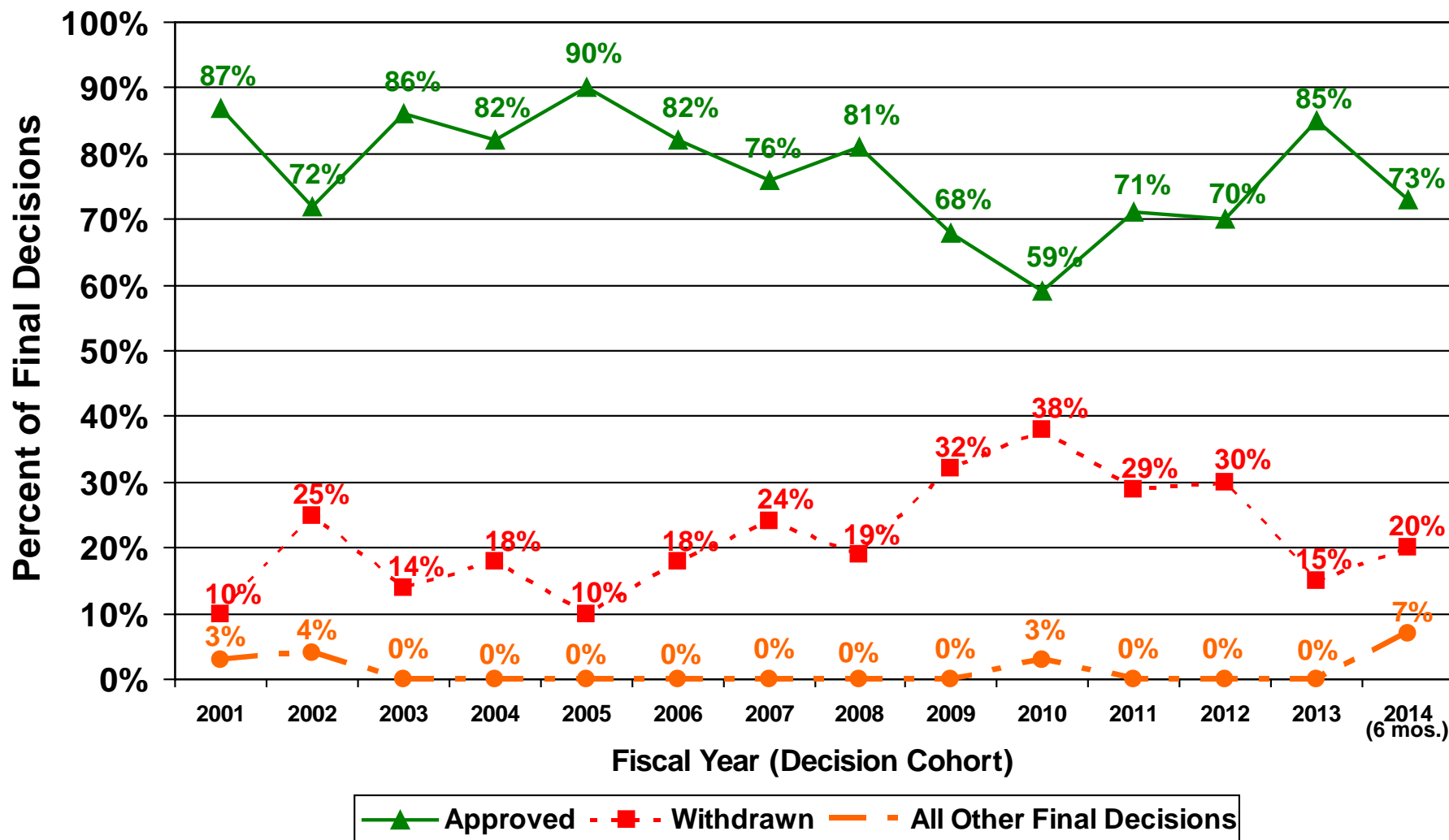
# PMAs Pending\* at End of Year



\*Original PMAs under review or on hold

\*\*Excludes FY 2013 and FY 2014 receipts that have not been accepted for substantive review; FY 2014 is as of 03/31/2014

# Percent of PMAs Approved\*



\*Based on original PMAs that were accepted for filing

**Quarterly Update on  
Medical Device Performance Goals  
MDUFA III Performance Data**

**October 1, 2012 – March 31, 2014**

Report prepared by Ellen Pinnow and the MDUFA III Performance Goal Report Team

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Steven Stone

Updated: 4/25/14

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## Acronyms and Abbreviations

510(k)	Premarket Notification
CDRH	Center for Devices and Radiologic Health
CLIA	Clinical Laboratory Improvement Act
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCTD	Division of Chemistry and Toxicology Devices
DIHD	Division of Immunology and Hematology Devices
DMD	Division of Microbiology Devices
DRH	Division of Radiological Health
DNPM	Division of Neurological and Physical Medicine Devices
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose and Throat Devices
DRGUD	Division of Reproductive, Gastro-Renal, and Urological Devices
DSD	Division of Surgical Devices
IDE	Investigational Device Exemption
MDUFA	Medical Device User Fee Act
NSE	Not Substantially Equivalent
ODE	Office of Device Evaluation
OIR	Office of In Vitro Diagnostics and Radiological Health
PMA	Premarket Application
RTA	Refuse to Accept
RTF	Refuse to File
SE	Substantially Equivalent
SI	Substantive Interaction

**Note: Data may change in subsequent quarterly and annual reports.**



## **Section 1 PMA Originals and Panel Track Supplements**

## PMA Originals and Panel Track Supplements – Center Level

**Table 1.1 CDRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34	19			
Closed before RTA action	1	0			
Number with accepted RTA review	26	12			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	4			
Number Not Accepted for Filing Review	6	3			
Rate of submissions not accepted for filing review	18%	20%			

\* RTA was not in place 1st quarter, thus data in Table 1.1 for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2 CDRH – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	44	19			
Number Accepted <sup>#</sup>	37	12			
Completed RTF	43	13			
Number Not Filed <sup>@</sup>	3	1			
Rate of submissions Not Filed	7%	8%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

**Table 1.3 CDRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	43	12			
SI Goal Met	41	9			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	3			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	95%	100%			

**Table 1.4 CDRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	43	9			
Average number of FDA days to Substantive Interaction	89	88			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	84	87			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	87	88			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	88			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	89			
Maximum FDA days to Substantive Interaction	117	90			

**Table 1.5 CDRH – PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	30	11			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	17	0			
MDUFA III Decisions Goal Met	17	0			
PMAs pending MDUFA III Decision	13	11			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	94%	N/A			

**Table 1.6 CDRH – PMA Originals & Panel Track Supplements (with Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	13	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	4	0			
MDUFA III Decisions Goal Met	4	0			
PMAs pending MDUFA III Decision	9	1			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	80%	N/A			

**Table 1.7 CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	17	0			
<b>Average FDA days to MDUFA III decision</b>	169				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	176				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	271				
<b>Average Industry days to MDUFA III decision</b>	64				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	55				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	92				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	230				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	235				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	269				
Maximum Total days to MDUFA III decision	371				

**Table 1.8 CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	4	0			
<b>Average FDA days to MDUFA III decision</b>	224				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	196				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	209				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	216				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	247				
Maximum FDA days to MDUFA III decision	290				
<b>Average Industry days to MDUFA III decision</b>	82				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	28				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	113				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	159				
Maximum Industry days to MDUFA III decision	186				
<b>Average Total days to MDUFA III decision</b>	306				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	256				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	297				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	316				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	356				
Maximum Total days to MDUFA III decision	405				

**Table 1.9 CDRH – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	30	11			
Number with MDUFA decision	17	0			
Number of Withdrawals	1	0			
Number of Not Approvable	3	0			
Rate of Withdrawals	6%	N/A			
Rate of Not Approvable	18%	N/A			

**Table 1.10 CDRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	13	1			
Number with MDUFA decision	4	0			
Number of Withdrawals	1	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	25%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11 CDRH – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12 CDRH – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



## PMA Originals and Panel Track Supplements – Office Level

**Table 1.1.ODE ODE – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	27	17			
Closed before RTA action	1	0			
Number with accepted RTA review	19	11			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	4			
Number Not Accepted for Filing Review	6	2			
Rate of submissions not accepted for filing review	23%	15%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.ODE for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.ODE ODE – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	34	17			
Number Accepted <sup>#</sup>	27	11			
Completed RTF	33	11			
Number Not Filed <sup>@</sup>	3	1			
Rate of submissions Not Filed	9%	9%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 2 PMA Original or Panel Track Supplements that were not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.ODE ODE – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	33	10			
SI Goal Met	31	8			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	94%	100%			

**Table 1.4.ODE ODE – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	33	8			
Average number of FDA days to Substantive Interaction	88	88			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	84	88			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	87	88			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	88			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	90			
Maximum FDA days to Substantive Interaction	117	90			

**Table 1.5.ODE ODE - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	24	9			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	12	0			
MDUFA III Decisions Goal Met	12	0			
PMAs pending MDUFA III Decision	12	9			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	92%	N/A			

**Table 1.6.ODE ODE – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA  
Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	9	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	3	0			
MDUFA III Decisions Goal Met	3	0			
PMAs pending MDUFA III Decision	6	1			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	75%	N/A			

**Table 1.7.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	12	0			
<b>Average FDA days to MDUFA III decision</b>	178				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	176				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	271				
<b>Average Industry days to MDUFA III decision</b>	46				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	55				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	92				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	226				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	235				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	269				
Maximum Total days to MDUFA III decision	371				

**Table 1.8.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	3	0			
<b>Average FDA days to MDUFA III decision</b>	230				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	197				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	212				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	233				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	262				
Maximum FDA days to MDUFA III decision	290				
<b>Average Industry days to MDUFA III decision</b>	109				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	56				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	113				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	150				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	168				
Maximum Industry days to MDUFA III decision	186				
<b>Average Total days to MDUFA III decision</b>	339				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	303				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	316				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	339				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	372				
Maximum Total days to MDUFA III decision	405				

**Table 1.9.ODE ODE – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	24	9			
Number with MDUFA decision	12	0			
Number of Withdrawals	1	0			
Number of Not Approvable	2	0			
Rate of Withdrawals	8%	N/A			
Rate of Not Approvable	17%	N/A			

**Table 1.10.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	9	1			
Number with MDUFA decision	3	0			
Number of Withdrawals	1	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	33%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11.ODE ODE – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.ODE ODE – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.OIR OIR – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	2			
Closed before RTA action	0	0			
Number with accepted RTA review	7	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	0%	50%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.OIR for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.OIR OIR – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	10	2			
Number Accepted <sup>#</sup>	10	1			
Completed RTF	10	2			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.



**Table 1.3.OIR OIR – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	10	2			
SI Goal Met	10	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4.OIR OIR – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	10	1			
Average number of FDA days to Substantive Interaction	89	83			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86	83			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	83			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	83			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	83			
Maximum FDA days to Substantive Interaction	112	83			

**Table 1.5.OIR OIR - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	6	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	5	0			
MDUFA III Decisions Goal Met	5	0			
PMAs pending MDUFA III Decision	1	2			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.OIR OIR – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA  
Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	4	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	3	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	5	0			
<b>Average FDA days to MDUFA III decision</b>	147				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	113				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	147				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	170				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	175				
Maximum FDA days to MDUFA III decision	177				
<b>Average Industry days to MDUFA III decision</b>	102				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	79				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	97				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	111				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	121				
Maximum Industry days to MDUFA III decision	133				
<b>Average Total days to MDUFA III decision</b>	249				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	211				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	236				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	262				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	289				
Maximum Total days to MDUFA III decision	307				

**Table 1.8.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

**Table 1.9.OIR OIR – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	6	2			
Number with MDUFA decision	5	0			
Number of Withdrawals	0	0			
Number of Not Approvable	1	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	20%	N/A			

**Table 1.10.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11.OIR OIR – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.OIR OIR – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA Originals and Panel Track Supplements – Division Level

**Table 1.1.DAGRID      DAGRID – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	0			
Closed before RTA action	0	0			
Number with accepted RTA review	0	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of submissions not accepted for filing review	100%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DAGRID for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DAGRID      DAGRID – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number Accepted <sup>#</sup>	1	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DAGRID      DAGRID – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	2	0			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DAGRID      DAGRID – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	85				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	84				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	87				



**Table 1.5.DAGRID      DAGRID - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6.DAGRID      DAGRID – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7.DAGRID      DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.8.DAGRID      DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DAGRID      DAGRID – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DAGRID      DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DAGRID    DAGRID – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DAGRID    DAGRID – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DCD DCD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	16	10			
Closed before RTA action	1	0			
Number with accepted RTA review	14	7			
Number without a RTA Review and > 15 Days since Date Received	1	0			
Number without a RTA Review and <= 15 Days since Date Received	0	3			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	0%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DCD DCD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	19	10			
Number Accepted <sup>#</sup>	18	7			
Completed RTF	18	6			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DCD DCD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	18	6			
SI Goal Met	17	5			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	94%	100%			

**Table 1.4.DCD DCD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	18	5			
Average number of FDA days to Substantive Interaction	88	88			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	83	88			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	87	88			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	88			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90	88			
Maximum FDA days to Substantive Interaction	117	89			

**Table 1.5.DCD DCD - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	15	5			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	10	0			
MDUFA III Decisions Goal Met	10	0			
PMAs pending MDUFA III Decision	5	5			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	91%	N/A			

**Table 1.6.DCD DCD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA  
Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	3	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	3	1			
PMAs pending MDUFA III Decision Past Goal	1	0			
Current Performance Percent Goal Met	0%	N/A			



**Table 1.7.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	10	0			
<b>Average FDA days to MDUFA III decision</b>	178				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	176				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	271				
<b>Average Industry days to MDUFA III decision</b>	58				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	21				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	73				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	97				
Maximum Industry days to MDUFA III decision	194				
<b>Average Total days to MDUFA III decision</b>	236				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	178				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	201				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	253				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	273				
Maximum Total days to MDUFA III decision	371				

**Table 1.8.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DCD DCD – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	15	5			
Number with MDUFA decision	10	0			
Number of Withdrawals	1	0			
Number of Not Approvable	2	0			
Rate of Withdrawals	10%	N/A			
Rate of Not Approvable	20%	N/A			

**Table 1.10.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	3	1			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DCD DCD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DCD DCD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DNPMD      DNPMD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	2			
Closed before RTA action	0	0			
Number with accepted RTA review	0	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	1	1			
Rate of submissions not accepted for filing review	100%	50%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2. DNPMD      DNPMD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	2			
Number Accepted <sup>#</sup>	0	1			
Completed RTF	1	2			
Number Not Filed	0	1			
Rate of submissions Not Filed	0%	50%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3. DNPMD      DNPMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	1	1			
SI Goal Met	0	1			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	0%	100%			

**Table 1.4. DNPMD      DNPMD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	1	1			
Average number of FDA days to Substantive Interaction	92	90			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	92	90			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	92	90			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	92	90			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	92	90			
Maximum FDA days to Substantive Interaction	92	90			

**Table 1.5. DNPMD      DNPMD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	1	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	0	1			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6. DNPMD      DNPMD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7. DNPMD      DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	180				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	180				
Maximum FDA days to MDUFA III decision	180				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	180				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	180				
Maximum Total days to MDUFA III decision	180				



**Table 1.8. DNPMD      DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9. DNPMD      DNPMD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10. DNPMD      DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11. DNPMD DNPMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12. DNPMD DNPMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DOD DOD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	1			
Closed before RTA action	0	0			
Number with accepted RTA review	0	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	1			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	N/A	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DOD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DOD DOD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DOD DOD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	2	0			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DOD DOD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	86				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86				
Maximum FDA days to Substantive Interaction	86				

**Table 1.5.DOD DOD - PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6.DOD DOD – PMA Originals & Panel Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.8.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	219				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	219				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	219				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	219				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	219				
Maximum FDA days to MDUFA III decision	219				
<b>Average Industry days to MDUFA III decision</b>	186				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	186				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	186				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	186				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	186				
Maximum Industry days to MDUFA III decision	186				
<b>Average Total days to MDUFA III decision</b>	405				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	405				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	405				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	405				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	405				
Maximum Total days to MDUFA III decision	405				



**Table 1.9.DOD DOD – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	1	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	100%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11.DOD DOD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DOD DOD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DOED DOED – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	0			
Closed before RTA action	0	0			
Number with accepted RTA review	4	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	1	0			
Rate of submissions not accepted for filing review	20%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DOED for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DOED DOED – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	0			
Number Accepted <sup>#</sup>	5	0			
Completed RTF	6	0			
Number Not Filed <sup>@</sup>	1	0			
Rate of submissions Not Filed	17%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.DOED DOED – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	6	0			
SI Goal Met	6	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DOED DOED – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	6	0			
Average number of FDA days to Substantive Interaction	89				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DOED DOED - PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	4	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	3	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.DOED DOED – PMA Originals & Panel Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions Goal Met	2	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7.DOE DOED – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	177				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
Maximum FDA days to MDUFA III decision	177				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	177				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	177				
Maximum Total days to MDUFA III decision	177				

**Table 1.8.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	2	0			
<b>Average FDA days to MDUFA III decision</b>	236				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	204				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	225				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	247				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	268				
Maximum FDA days to MDUFA III decision	290				
<b>Average Industry days to MDUFA III decision</b>	71				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	28				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	56				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	85				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	113				
Maximum Industry days to MDUFA III decision	141				
<b>Average Total days to MDUFA III decision</b>	307				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	297				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	303				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	310				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	316				
Maximum Total days to MDUFA III decision	323				

**Table 1.9.DOE DOED – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	4	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.DOE DOED – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	2	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			



**Table 1.11.DOED DOED – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DOED DOED – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DRGUD DRGUD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Closed before RTA action	0	0			
Number with accepted RTA review	1	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	3	0			
Rate of submissions not accepted for filing review	75%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRGUD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DRGUD DRGUD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Number Accepted <sup>#</sup>	1	0			
Completed RTF <sup>@</sup>	4	0			
Number Not Filed	2	0			
Rate of submissions Not Filed	50%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

<sup>@</sup> Note 1 PMA Original or Panel Track Supplement that was not filed 1st round was filed in a subsequent RTF review.

**Table 1.3.DRGUD DRGUD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	4	0			
SI Goal Met	4	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DRGUD DRGUD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	4	0			
Average number of FDA days to Substantive Interaction	89				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	88				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	89				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DRGUD      DRGUD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6.DRGUD      DRGUD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7.DRGUD      DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.8.DRGUD      DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DRGUD      DRGUD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DRGUD      DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DRGUD     DRGUD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DRGUD     DRGUD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



**Table 1.1.DSD                      DSD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	4			
Closed before RTA action	0	0			
Number with accepted RTA review	0	3			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	N/A	25%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DSD                      DSD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	0	4			
Number Accepted <sup>#</sup>	0	3			
Completed RTF	0	3			
Number Not Filed	0	0			
Rate of submissions Not Filed	N/A	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DSD DSD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>  65% SI within 90 FDA days	<b>FY 2014</b>  75% SI within 90 FDA Days	<b>FY 2015</b>  85% SI within 90 FDA Days	<b>FY 2016</b>  95% SI within 90 FDA Days	<b>FY 2017</b>  95% SI within 90 FDA Days
Eligible for SI	0	3			
SI Goal Met	0	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	N/A	100%			

**Table 1.4.DSD DSD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	0	2			
Average number of FDA days to Substantive Interaction		88			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction		86			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction		87			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction		88			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction		89			
Maximum FDA days to Substantive Interaction		90			

**Table 1.5.DSD                      DSD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	0	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	0	3			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.6.DSD                      DSD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7.DSD                      DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.8.DSD                      DSD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DSD                      DSD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	0	3			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DSD                      DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DSD      DSD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DSD      DSD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DCTD      DCTD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Closed before RTA action	0	0			
Number with accepted RTA review	2	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DCTD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DCTD      DCTD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.



**Table 1.3.DCTD DCTD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	0			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DCTD DCTD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	90				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DCTD      DCTD - PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.DCTD      DCTD – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	0	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7.DCTD      DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	174				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	174				
Maximum FDA days to MDUFA III decision	174				
<b>Average Industry days to MDUFA III decision</b>	133				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	133				
Maximum Industry days to MDUFA III decision	133				
<b>Average Total days to MDUFA III decision</b>	307				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	307				
Maximum Total days to MDUFA III decision	307				

**Table 1.8.DCTD      DCTD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DCTD      DCTD – PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	2	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.10.DCTD      DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Filed	0	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DCTD      DCTD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DCTD      DCTD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DIHD DIHD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	0			
Closed before RTA action	0	0			
Number with accepted RTA review	2	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	N/A			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DIHD for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DIHD DIHD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	0			
Number Accepted <sup>#</sup>	4	0			
Completed RTF	4	0			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	N/A			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DIHD DIHD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	4	0			
SI Goal Met	4	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DIHD DIHD – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	4	0			
Average number of FDA days to Substantive Interaction	95				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	90				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	99				
Maximum FDA days to Substantive Interaction	112				



**Table 1.5.DIHD DIHD - PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions Goal Met	2	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.DIHD DIHD – PMA Originals & Panel Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	2	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	2	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 1.7.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	2	0			
<b>Average FDA days to MDUFA III decision</b>	108				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	102				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	106				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	109				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	113				
Maximum FDA days to MDUFA III decision	116				
<b>Average Industry days to MDUFA III decision</b>	95				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	80				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	90				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	99				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	109				
Maximum Industry days to MDUFA III decision	118				
<b>Average Total days to MDUFA III decision</b>	202				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	193				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	199				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	205				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	211				
Maximum Total days to MDUFA III decision	217				

**Table 1.8.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DIHD DIHD – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	2	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	2	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11.DIHD DIHD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DIHD DIHD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DMD DMD – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Closed before RTA action	0	0			
Number with accepted RTA review	2	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	0			
Rate of submissions not accepted for filing review	0%	0%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DMD DMD – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Number Accepted <sup>#</sup>	2	1			
Completed RTF	2	1			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DMD DMD – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	1			
SI Goal Met	2	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 1.4.DRH DMD – DMD Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	1			
Average number of FDA days to Substantive Interaction	86	83			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	86	83			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	86	83			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	86	83			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	86	83			
Maximum FDA days to Substantive Interaction	86	83			

**Table 1.5.DMD DMD - PMA Originals & Panel-Track Supplements (without Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	1	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	0	1			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.DMD DMD – PMA Originals & Panel Track Supplements (with Panel Review)**  
**MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			



**Table 1.7.DMD DMD – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	177				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	177				
Maximum FDA days to MDUFA III decision	177				
<b>Average Industry days to MDUFA III decision</b>	107				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	107				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	107				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	107				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	107				
Maximum Industry days to MDUFA III decision	107				
<b>Average Total days to MDUFA III decision</b>	284				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	284				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	284				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	284				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	284				
Maximum Total days to MDUFA III decision	284				

**Table 1.8.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	0	0			
<b>Average FDA days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile FDA days to MDUFA III decision					
40 <sup>th</sup> Percentile FDA days to MDUFA III decision					
60 <sup>th</sup> Percentile FDA days to MDUFA III decision					
80 <sup>th</sup> Percentile FDA days to MDUFA III decision					
Maximum FDA days to MDUFA III decision					
<b>Average Industry days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Industry days to MDUFA III decision					
40 <sup>th</sup> Percentile Industry days to MDUFA III decision					
60 <sup>th</sup> Percentile Industry days to MDUFA III decision					
80 <sup>th</sup> Percentile Industry days to MDUFA III decision					
Maximum Industry days to MDUFA III decision					
<b>Average Total days to MDUFA III decision</b>					
20 <sup>th</sup> Percentile Total days to MDUFA III decision					
40 <sup>th</sup> Percentile Total days to MDUFA III decision					
60 <sup>th</sup> Percentile Total days to MDUFA III decision					
80 <sup>th</sup> Percentile Total days to MDUFA III decision					
Maximum Total days to MDUFA III decision					

**Table 1.9.DMD DMD – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.10.DMD DMD – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	N/A	N/A			
Rate of Not Approvable	N/A	N/A			

**Table 1.11. DMD      DMD – PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DMD      DMD – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.1.DRH DRH – PMA Original and Panel Track Supplements – Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	1			
Closed before RTA action	0	0			
Number with accepted RTA review	1	0			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	0			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	0%	100%			

\* RTA was not in place 1st quarter, thus data in Table 1.1.DRH for FY2013 includes only PMA Original and Panel Track Supplements received on or after January 1, 2013. All other tables include PMA Original and Panel Track Supplements received on or after October 1, 2012.

**Table 1.2.DRH DRH – PMA Original and Panel Track Supplements – Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	1			
Number Accepted <sup>#</sup>	2	0			
Completed RTF	2	1			
Number Not Filed	0	0			
Rate of submissions Not Filed	0%	0%			

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013.

**Table 1.3.DRH DRH – PMA Originals & Panel Track Supplements - Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	2	1			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 1.4.DRH DRH – PMA Originals and Panel Track Supplements - Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2	0			
Average number of FDA days to Substantive Interaction	78				
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	70				
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	75				
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	80				
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	85				
Maximum FDA days to Substantive Interaction	90				

**Table 1.5.DRH DRH - PMA Originals & Panel-Track Supplements (without Panel Review)  
MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 70% within 180 FDA days	<b>FY 2014</b> 80% within 180 FDA days	<b>FY 2015</b> 80% within 180 FDA days	<b>FY 2016</b> 90% within 180 FDA days	<b>FY 2017</b> 90% within 180 FDA days
Number of PMAs filed	1	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	0	1			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.6.DRH DRH – PMA Originals & Panel Track Supplements (with Panel Review) MDUFA  
Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 50% within 320 FDA days	<b>FY 2014</b> 70% within 320 FDA days	<b>FY 2015</b> 80% within 320 FDA days	<b>FY 2016</b> 80% within 320 FDA days	<b>FY 2017</b> 90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
PMAs pending MDUFA III Decision	0	0			
PMAs pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 1.7.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	167				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	167				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	167				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	167				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	167				
Maximum FDA days to MDUFA III decision	167				
<b>Average Industry days to MDUFA III decision</b>	81				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	81				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	81				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	81				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	81				
Maximum Industry days to MDUFA III decision	81				
<b>Average Total days to MDUFA III decision</b>	248				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	248				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	248				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	248				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	248				
Maximum Total days to MDUFA III decision	248				



**Table 1.8.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA decision	1	0			
<b>Average FDA days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
40 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
60 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
80 <sup>th</sup> Percentile FDA days to MDUFA III decision	206				
Maximum FDA days to MDUFA III decision	206				
<b>Average Industry days to MDUFA III decision</b>	0				
20 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
40 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
60 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
80 <sup>th</sup> Percentile Industry days to MDUFA III decision	0				
Maximum Industry days to MDUFA III decision	0				
<b>Average Total days to MDUFA III decision</b>	206				
20 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
40 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
60 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
80 <sup>th</sup> Percentile Total days to MDUFA III decision	206				
Maximum Total days to MDUFA III decision	206				

**Table 1.9.DRH DRH – PMA Originals and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	1	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	100%	N/A			

**Table 1.10.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	1	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0%	N/A			
Rate of Not Approvable	0%	N/A			

**Table 1.11.DRH DRH – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 1.12.DRH DRH – PMA Original and Panel Track Supplements (with Panel Review)**  
**Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## **Section 2 PMA 180 Day Supplements**

## PMA 180 Day Supplements – Center Level

**Table 2.1 CDRH – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	182^	70			
SI Goal Met	168	44			
SI Goal Not Met	11	0			
SI Pending Within Goal	0	24			
SI Pending Past Goal	0	2			
Closed without SI	3^	0			
Current SI Performance Percent Goal Met	94%	96%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2 CDRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	182^	70			
Non-MDUFA III Decisions	5	0			
MDUFA III Decisions	151	18			
MDUFA III Decisions Goal Met	149	18			
Supplements pending MDUFA III Decision	26	52			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	99%	100%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3 CDRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	182^	70			
Number with MDUFA decision	151	18			
Number of Not Approvable	7	0			
Rate of Not Approvable	5%	0%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.4 CDRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	198				
Mean Industry days for submissions that missed goal	182				

## PMA 180 Day Supplements – Office Level

**Table 2.1.ODE ODE – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 90 FDA days	75% SI within 90 FDA Days	85% SI within 90 FDA Days	95% SI within 90 FDA Days	95% SI within 90 FDA Days
Eligible for SI	161^	65			
SI Goal Met	147	41			
SI Goal Not Met	11	0			
SI Pending Within Goal	0	22			
SI Pending Past Goal	0	2			
Closed without SI	3	0			
Current SI Performance Percent Goal Met	93%	95%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2.ODE ODE – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	161^	65			
Non-MDUFA III Decisions	5	0			
MDUFA III Decisions	135	17			
MDUFA III Decisions Goal Met	133	17			
Supplements pending MDUFA III Decision	21	48			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	99%	100%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3.ODE ODE – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	161^	65			
Number with MDUFA decision	135	17			
Number of Not Approvable	7	0			
Rate of Not Approvable	5%	0%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.4.ODE ODE – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	198				
Mean Industry days for submissions that missed goal	182				



**Table 2.1.OIR OIR – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	21	5			
SI Goal Met	21	3			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 2.2.OIR OIR – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	21	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	16	1			
MDUFA III Decisions Goal Met	16	1			
Supplements pending MDUFA III Decision	5	4			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3.OIR    OIR – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	21	5			
Number with MDUFA decision	16	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 2.4.OIR    OIR – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA 180 Day Supplements – Division Level

**Table 2.1.DAGRID      DAGRID – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	9	3			
SI Goal Met	7	1			
SI Goal Not Met	2	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	78%	100%			

**Table 2.2.DAGRID      DAGRID – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	9	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	6	0			
MDUFA III Decisions Goal Met	5	0			
Supplements pending MDUFA III Decision	3	3			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	83%	N/A			

**Table 2.3.DAGRID      DAGRID – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	9	3			
Number with MDUFA decision	6	0			
Number of Not Approvable	1	0			
Rate of Not Approvable	17%	N/A			

**Table 2.4.DAGRID      DAGRID – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	213				
Mean Industry days for submissions that missed goal	276				

**Table 2.1.DCD DCD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	116^	37			
SI Goal Met	108	29			
SI Goal Not Met	5	0			
SI Pending Within Goal	0	8			
SI Pending Past Goal	0	0			
Closed without SI	3	0			
Current SI Performance Percent Goal Met	96%	100%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.2.DCD DCD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	116^	37			
Non-MDUFA III Decisions	4	0			
MDUFA III Decisions	103	15			
MDUFA III Decisions Goal Met	102	15			
Supplements pending MDUFA III Decision	9	22			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	99%	100%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.3.DCD DCD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	116^	37			
Number with MDUFA decision	103	15			
Number of Not Approvable	4	0			
Rate of Not Approvable	4%	0%			

^ Includes one PMA 180 Day Supplement that was converted.

**Table 2.4.DCD DCD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	182				
Mean Industry days for submissions that missed goal	0				

**Table 2.1.DNPMD      DNPMD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	8	7			
SI Goal Met	7	3			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	88%	100%			

**Table 2.2.DNPMD      DNPMD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	8	7			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	6	1			
MDUFA III Decisions Goal Met	6	1			
Supplements pending MDUFA III Decision	1	6			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3.DNPMD      DNPMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	8	7			
Number with MDUFA decision	6	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	17%	0%			

**Table 2.4.DNPMD      DNPMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



**Table 2.1.DOD DOD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	2	2			
SI Goal Met	2	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	2			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 2.2.DOD DOD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	2	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions Goal Met	0	0			
Supplements pending MDUFA III Decision	2	2			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	N/A			

**Table 2.3.DOD DOD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2	2			
Number with MDUFA decision	0	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	N/A			

**Table 2.4.DOD DOD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DOED DOED – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	12	9			
SI Goal Met	11	5			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	4			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	92%	100%			

**Table 2.2.DOED DOED – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	12	9			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	10	1			
MDUFA III Decisions Goal Met	10	1			
Supplements pending MDUFA III Decision	2	8			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3.DOED DOED – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	12	9			
Number with MDUFA decision	10	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	10%	0%			

**Table 2.4.DOED DOED – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DRGUD      DRGUD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	10	3			
SI Goal Met	9	2			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	90%	100%			

**Table 2.2.DRGUD      DRGUD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	10	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	8	0			
MDUFA III Decisions Goal Met	8	0			
Supplements pending MDUFA III Decision	2	3			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 2.3.DRGUD      DRGUD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	10	3			
Number with MDUFA decision	8	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DRGUD      DRGUD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DSD DSD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	4	4			
SI Goal Met	3	1			
SI Goal Not Met	1	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	2			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	75%	33%			

**Table 2.2.DSD DSD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	4	4			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions Goal Met	2	0			
Supplements pending MDUFA III Decision	2	4			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 2.3.DSD DSD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	4	4			
Number with MDUFA decision	2	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DSD DSD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



**Table 2.1.DCTD DCTD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	3	0			
SI Goal Met	3	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 2.2.DCTD DCTD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	3	0			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	1	0			
MDUFA III Decisions Goal Met	1	0			
Supplements pending MDUFA III Decision	2	0			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 2.3.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	0			
Number with MDUFA decision	1	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DCTD DCTD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DIHD DIHD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	6	3			
SI Goal Met	6	2			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 2.2.DIHD DIHD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	6	3			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	6	0			
MDUFA III Decisions Goal Met	6	0			
Supplements pending MDUFA III Decision	0	3			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 2.3.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	6	3			
Number with MDUFA decision	6	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DIHD DIHD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DMD DMD – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	7	1			
SI Goal Met	7	0			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	1			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	N/A			

**Table 2.2.DMD DMD – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	7	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	5	0			
MDUFA III Decisions Goal Met	5	0			
Supplements pending MDUFA III Decision	2	1			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	N/A			

**Table 2.3.DMD DMD – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	7	1			
Number with MDUFA decision	5	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	N/A			

**Table 2.4.DMD DMD – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 2.1.DRH DRH – PMA 180 Day Supplements Substantive Interaction Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b> 65% SI within 90 FDA days	<b>FY 2014</b> 75% SI within 90 FDA Days	<b>FY 2015</b> 85% SI within 90 FDA Days	<b>FY 2016</b> 95% SI within 90 FDA Days	<b>FY 2017</b> 95% SI within 90 FDA Days
Eligible for SI	5	1			
SI Goal Met	5	1			
SI Goal Not Met	0	0			
SI Pending Within Goal	0	0			
SI Pending Past Goal	0	0			
Closed without SI	0	0			
Current SI Performance Percent Goal Met	100%	100%			

**Table 2.2.DRH DRH – PMA 180 Day Supplements MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 85% within 180 FDA days	<b>FY 2014</b> 90% within 180 FDA days	<b>FY 2015</b> 90% within 180 FDA days	<b>FY 2016</b> 95% within 180 FDA days	<b>FY 2017</b> 95% within 180 FDA days
Supplements received	5	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	4	1			
MDUFA III Decisions Goal Met	4	1			
Supplements pending MDUFA III Decision	1	0			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 2.3.DRH DRH – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	5	1			
Number with MDUFA decision	4	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 2.4.DRH DRH – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



## **Section 3 PMA Real Time Supplements**

## PMA Real Time Supplements – Center Level

**Table 3.1 CDRH – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	305	165			
Non-MDUFA III Decisions	9	4			
MDUFA III Decisions	296	61			
MDUFA III Decisions Goal Met	294	61			
Supplements pending MDUFA III Decision	0	100			
Supplements pending MDUFA III Decision Past Goal	0	3			
Current Performance Percent Goal Met	99%	95%			

**Table 3.2 CDRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	305	165			
Number with MDUFA decision	296	61			
Number of Not Approvable	20	0			
Rate of Not Approvable	7%	0%			

**Table 3.3 CDRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	143				
Mean Industry days for submissions that missed goal	0				

## PMA Real Time Supplements – Office Level

**Table 3.1.ODE ODE – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	266	139			
Non-MDUFA III Decisions	8	2			
MDUFA III Decisions	258	51			
MDUFA III Decisions Goal Met	256	51			
Supplements pending MDUFA III Decision	0	86			
Supplements pending MDUFA III Decision Past Goal	0	3			
Current Performance Percent Goal Met	99%	94%			

**Table 3.2.ODE ODE – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	266	139			
Number with MDUFA decision	258	51			
Number of Not Approvable	15	0			
Rate of Not Approvable	6%	0%			

**Table 3.3.ODE ODE – Real Time PMA Supplements Performance Metrics – Submissions  
Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	143				
Mean Industry days for submissions that missed goal	0				

**Table 3.1.OIR OIR – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	39	26			
Non-MDUFA III Decisions	1	2			
MDUFA III Decisions	38	10			
MDUFA III Decisions Goal Met	38	10			
Supplements pending MDUFA III Decision	0	14			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.OIR OIR – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	39	26			
Number with MDUFA decision	38	10			
Number of Not Approvable	5	0			
Rate of Not Approvable	13%	0%			

**Table 3.3.OIR OIR – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## PMA Real Time Supplements – Division Level

**Table 3.1.DAGRID      DAGRID – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	13	5			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	1			
MDUFA III Decisions Goal Met	13	1			
Supplements pending MDUFA III Decision	0	4			
Supplements pending MDUFA III Decision Past Goal	0	1			
Current Performance Percent Goal Met	100%	50%			

**Table 3.2.DAGRID      DAGRID – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	5			
Number with MDUFA decision	13	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	8%	0%			

**Table 3.3.DAGRID      DAGRID – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



**Table 3.1.DCD DCD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	174	105			
Non-MDUFA III Decisions	6	2			
MDUFA III Decisions	168	39			
MDUFA III Decisions Goal Met	168	39			
Supplements pending MDUFA III Decision	0	64			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DCD DCD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	174	105			
Number with MDUFA decision	168	39			
Number of Not Approvable	7	0			
Rate of Not Approvable	4%	0%			

**Table 3.3.DCD DCD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DNPMD      DNPMD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	23	6			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	23	2			
MDUFA III Decisions Goal Met	23	2			
Supplements pending MDUFA III Decision	0	4			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DNPMD      DNPMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	23	6			
Number with MDUFA decision	23	2			
Number of Not Approvable	1	0			
Rate of Not Approvable	4%	0%			

**Table 3.3.DNPMD      DNPMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DOD DOD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	8	8			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	8	3			
MDUFA III Decisions Goal Met	8	3			
Supplements pending MDUFA III Decision	0	5			
Supplements pending MDUFA III Decision Past Goal	0	2			
Current Performance Percent Goal Met	100%	60%			

**Table 3.2.DOD DOD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	8	8			
Number with MDUFA decision	8	3			
Number of Not Approvable	2	0			
Rate of Not Approvable	25%	0%			

**Table 3.3.DOD DOD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DOED DOED – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	16	6			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	16	1			
MDUFA III Decisions Goal Met	16	1			
Supplements pending MDUFA III Decision	0	5			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DOED DOED – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	16	6			
Number with MDUFA decision	16	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3.DOED DOED – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DRGUD      DRGUD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	19	2			
Non-MDUFA III Decisions	2	0			
MDUFA III Decisions	17	1			
MDUFA III Decisions Goal Met	17	1			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DRGUD      DRGUD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	19	2			
Number with MDUFA decision	17	1			
Number of Not Approvable	1	0			
Rate of Not Approvable	6%	0%			

**Table 3.3.DRGUD      DRGUD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DSD DSD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	13	7			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	4			
MDUFA III Decisions Goal Met	11	4			
Supplements pending MDUFA III Decision	0	3			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	85%	100%			

**Table 3.2.DSD DSD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	7			
Number with MDUFA decision	13	4			
Number of Not Approvable	3	0			
Rate of Not Approvable	23%	0%			

**Table 3.3.DSD DSD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	2	0			
Mean FDA days for submissions that missed goal	143				
Mean Industry days for submissions that missed goal	0				

**Table 3.1.DCTD DCTD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	6	10			
Non-MDUFA III Decisions	0	2			
MDUFA III Decisions	6	5			
MDUFA III Decisions Goal Met	6	5			
Supplements pending MDUFA III Decision	0	3			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	6	10			
Number with MDUFA decision	6	5			
Number of Not Approvable	0	0			
Rate of Not Approvable	0%	0%			

**Table 3.3.DCTD DCTD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DIHD DIHD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	20	13			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	19	3			
MDUFA III Decisions Goal Met	19	3			
Supplements pending MDUFA III Decision	0	10			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	20	13			
Number with MDUFA decision	19	3			
Number of Not Approvable	2	0			
Rate of Not Approvable	11%	0%			

**Table 3.3.DIHD DIHD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					



**Table 3.1.DMD DMD – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	13	2			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	13	1			
MDUFA III Decisions Goal Met	13	1			
Supplements pending MDUFA III Decision	0	1			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	100%	100%			

**Table 3.2.DMD DMD – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	13	2			
Number with MDUFA decision	13	1			
Number of Not Approvable	3	0			
Rate of Not Approvable	23%	0%			

**Table 3.3.DMD DMD – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 3.1.DRH DRH – Real Time PMA Supplements MDUFA Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b> 90% within 90 FDA days	<b>FY 2014</b> 90% within 90 FDA days	<b>FY 2015</b> 95% within 90 FDA days	<b>FY 2016</b> 95% within 90 FDA days	<b>FY 2017</b> 95% within 90 FDA days
Supplements received	0	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	0	1			
MDUFA III Decisions Goal Met	0	1			
Supplements pending MDUFA III Decision	0	0			
Supplements pending MDUFA III Decision Past Goal	0	0			
Current Performance Percent Goal Met	N/A	100%			

**Table 3.2.DRH DRH – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	0	1			
Number with MDUFA decision	0	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	N/A	0%			

**Table 3.3.DRH DRH – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

## **Section 4 Pre-Market Report Submissions**

There were no pre-market reports received by FDA between October 1, 2012 and March 31, 2014.

## **Section 5 PMA Annual Metrics and Goals**

PMA Annual Metrics and Goals will be reported in the Annual Report.

## **Section 6 510(k) MDUFA III Performance**

## 510(k) MDUFA III Performance – Center Level

**Table 6.1 CDRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,964	1,712			
Closed before RTA action	11	4			
Number Accepted	1,197	712			
RTA Review not done and > 15 days since Date Received	41	28			
RTA Review not done and <= 15 days since Date Received	0	95			
Number Not Accepted	1,715	873			
Rate of submissions not accepted	58%	54%			

\* RTA was not in place 1st quarter, thus Table 6.1 for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2 CDRH – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	3693	1294			
Deleted or withdrawn prior to SI	11	0			
SI within 60 FDA days	3419	882			
SI over 60 FDA days	219	34			
SI pending within 60 FDA days	38	375			
SI pending over 60 FDA days	1	1			
510(k)s NSE without SI	5	2			
Current SI Performance Percent within 60 FDA days	94%	96%			

**Table 6.3 CDRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	3,638	916			
Average number of FDA days to Substantive Interaction	48	47			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	48	48			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	59			
Maximum FDA days to Substantive Interaction	98	93			

**Table 6.4 CDRH – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	3821	1332			
Non-MDUFA III Decisions	358	11			
MDUFA III Decisions (SE/NSE)	2,997	455			
MDUFA III Decisions within 90 FDA Days	2,952	451			
510(k)s pending MDUFA III Decision	466	866			
510(k) pending MDUFA III Decision over 90 FDA days	6	1			
Current Performance Percent within 90 FDA Days	98%	99%			

**Table 6.5 CDRH – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.4			
Number with MDUFA decision	2997	455			
<b>Average FDA days to MDUFA III decision</b>	69	56			
20th Percentile FDA days to MDUFA III decision	43	29			
40th Percentile FDA days to MDUFA III decision	71	47			
60th Percentile FDA days to MDUFA III decision	85	60			
80th Percentile FDA days to MDUFA III decision	89	85			
Maximum FDA days to MDUFA III decision	200	137			
<b>Average Industry days to MDUFA III decision</b>	45	9			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	8	0			
60th Percentile Industry days to MDUFA III decision	34	0			
80th Percentile Industry days to MDUFA III decision	83	21			
Maximum Industry days to MDUFA III decision	370	80			
<b>Average Total days to MDUFA III decision</b>	114	65			
20th Percentile Total days to MDUFA III decision	50	29			
40th Percentile Total days to MDUFA III decision	87	51			
60th Percentile Total days to MDUFA III decision	116	76			
80th Percentile Total days to MDUFA III decision	167	93			
Maximum Total days to MDUFA III decision	508	149			



**Table 6.6 CDRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3821	1332			
Number with MDUFA decision	2,997	455			
Number of SE decisions	2,895	448			
Number of NSE decisions	102	7			
Number of Withdrawals	173	2			
Number deleted	164	0			
Rate of SE decisions	97%	99%			
Rate of NSE decisions	3%	2%			
Rate of Withdrawals	5%	0.2%			
Rate of Deleted	4%	0%			

**Table 6.7 CDRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	45	4			
Mean FDA days for submissions that missed goal	109	106			
Mean Industry days for submissions that missed goal	101	2			

## 510(k) MDUFA III Performance – Office Level

**Table 6.1.ODE ODE – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	2,388	1378			
Closed before RTA action	9	4			
Number Accepted	821	503			
RTA Review not done and > 15 days since Date Received	23	24			
RTA Review not done and <= 15 days since Date Received	0	78			
Number Not Accepted	1,535	769			
Rate of submissions not accepted	65%	59%			

\* RTA was not in place 1st quarter, thus Table 6.1.ODE for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.ODE ODE – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	2933	1023			
Deleted or withdrawn prior to SI	10	0			
SI within 60 FDA days	2708	678			
SI over 60 FDA days	176	29			
SI pending within 60 FDA days	33	313			
SI pending over 60 FDA days	1	1			
510(k)s NSE without SI	5	2			
Current SI Performance Percent within 60 FDA days	94%	95%			

**Table 6.3.ODE ODE – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	2,884	707			
Average number of FDA days to Substantive Interaction	48	48			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	49	50			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	59			
Maximum FDA days to Substantive Interaction	98	90			

**Table 6.4.ODE ODE – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	3007	1045			
Non-MDUFA III Decisions	301	10			
MDUFA III Decisions (SE/NSE)	2,317	335			
MDUFA III Decisions within 90 FDA Days	2,277	335			
510(k)s pending MDUFA III Decision	389	700			
510(k) pending MDUFA III Decision over 90 FDA days	6	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.ODE ODE – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.4			
Number with MDUFA decision	2317	335			
<b>Average FDA days to MDUFA III decision</b>	71	57			
20th Percentile FDA days to MDUFA III decision	49	29			
40th Percentile FDA days to MDUFA III decision	75	50			
60th Percentile FDA days to MDUFA III decision	86	62			
80th Percentile FDA days to MDUFA III decision	89	86			
Maximum FDA days to MDUFA III decision	200	90			
<b>Average Industry days to MDUFA III decision</b>	46	9			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	12	0			
60th Percentile Industry days to MDUFA III decision	35	0			
80th Percentile Industry days to MDUFA III decision	83	21			
Maximum Industry days to MDUFA III decision	370	64			
<b>Average Total days to MDUFA III decision</b>	116	66			
20th Percentile Total days to MDUFA III decision	57	29			
40th Percentile Total days to MDUFA III decision	90	55			
60th Percentile Total days to MDUFA III decision	119	78			
80th Percentile Total days to MDUFA III decision	168	94			
Maximum Total days to MDUFA III decision	508	149			

**Table 6.6.ODE ODE – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	3,007	1045			
Number with MDUFA decision	2,317	335			
Number of SE decisions	2,233	332			
Number of NSE decisions	84	3			
Number of Withdrawals	144	1			
Number deleted	138	0			
Rate of SE decisions	96%	99%			
Rate of NSE decisions	4%	1%			
Rate of Withdrawals	5%	0.1%			
Rate of Deleted	5%	0%			

**Table 6.7.ODE ODE – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	40	0			
Mean FDA days for submissions that missed goal	110				
Mean Industry days for submissions that missed goal	102				

**Table 6.1.OIR OIR – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	576	334			
Closed before RTA action	2	0			
Number Accepted	376	209			
RTA Review not done and > 15 days since Date Received	18	4			
RTA Review not done and <= 15 days since Date Received	0	17			
Number Not Accepted	180	104			
Rate of submissions not accepted	31%	33%			

\* RTA was not in place 1st quarter, thus Table 6.1.OIR for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.OIR OIR – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013 65% SI within 60 FDA days	FY 2014 75% SI within 60 FDA Days	FY 2015 85% SI within 60 FDA Days	FY 2016 95% SI within 60 FDA Days	FY 2017 95% SI within 60 FDA Days
Eligible for SI	760	271			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	711	204			
SI over 60 FDA days	43	5			
SI pending within 60 FDA days	5	62			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	94%	98%			

**Table 6.3.OIR OIR – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	754	209			
Average number of FDA days to Substantive Interaction	45	45			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	29	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	43			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	51	52			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	58			
Maximum FDA days to Substantive Interaction	91	93			

**Table 6.4.OIR OIR – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	814	287			
Non-MDUFA III Decisions	57	1			
MDUFA III Decisions (SE/NSE)	680	120			
MDUFA III Decisions within 90 FDA Days	675	116			
510(k)s pending MDUFA III Decision	77	166			
510(k) pending MDUFA III Decision over 90 FDA days	0	1			
Current Performance Percent within 90 FDA Days	99%	96%			

**Table 6.5.OIR OIR – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.6	1.3			
Number with MDUFA decision	680	120			
<b>Average FDA days to MDUFA III decision</b>	62	53			
20th Percentile FDA days to MDUFA III decision	33	29			
40th Percentile FDA days to MDUFA III decision	55	41			
60th Percentile FDA days to MDUFA III decision	79	58			
80th Percentile FDA days to MDUFA III decision	87	82			
Maximum FDA days to MDUFA III decision	121	137			
<b>Average Industry days to MDUFA III decision</b>	44	10			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	27	0			
80th Percentile Industry days to MDUFA III decision	86	21			
Maximum Industry days to MDUFA III decision	357	80			
<b>Average Total days to MDUFA III decision</b>	106	63			
20th Percentile Total days to MDUFA III decision	34	29			
40th Percentile Total days to MDUFA III decision	73	44			
60th Percentile Total days to MDUFA III decision	99	72			
80th Percentile Total days to MDUFA III decision	161	92			
Maximum Total days to MDUFA III decision	447	149			



**Table 6.6.OIR OIR – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	814	287			
Number with MDUFA decision	680	120			
Number of SE decisions	662	116			
Number of NSE decisions	18	4			
Number of Withdrawals	29	1			
Number deleted	26	0			
Rate of SE decisions	97%	97%			
Rate of NSE decisions	3%	3%			
Rate of Withdrawals	4%	0.3%			
Rate of Deleted	3%	0%			

**Table 6.7.OIR OIR – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	5	4			
Mean FDA days for submissions that missed goal	104	106			
Mean Industry days for submissions that missed goal	99	2			

## 510(k) MDUFA III Performance – Division Level

**Table 6.1.DAGRID      DAGRID – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	637	347			
Closed before RTA action	6	1			
Number Accepted	189	105			
RTA Review not done and > 15 days since Date Received	5	8			
RTA Review not done and <= 15 days since Date Received	0	21			
Number Not Accepted	437	212			
Rate of submissions not accepted	69%	65%			

\* RTA was not in place 1st quarter, thus Table 6.1.DAGRID for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DAGRID      DAGRID – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	763	235			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	725	145			
SI over 60 FDA days	25	0			
SI pending within 60 FDA days	10	90			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	3	0			
Current SI Performance Percent within 60 FDA days	96%	100%			

**Table 6.3.DAGRID      DAGRID – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	750	145			
Average number of FDA days to Substantive Interaction	51	51			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	42	40			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	54	56			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	58			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	60	60			
Maximum FDA days to Substantive Interaction	90	60			

**Table 6.4.DAGRID      DAGRID – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	778	241			
Non-MDUFA III Decisions	103	4			
MDUFA III Decisions (SE/NSE)	543	43			
MDUFA III Decisions within 90 FDA Days	531	43			
510(k)s pending MDUFA III Decision	132	194			
510(k) pending MDUFA III Decision over 90 FDA days	3	0			
Current Performance Percent within 90 FDA Days	97%	100%			

**Table 6.5.DAGRID      DAGRID – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.4			
Number with MDUFA decision	543	43			
<b>Average FDA days to MDUFA III decision</b>	76	66			
20th Percentile FDA days to MDUFA III decision	59	28			
40th Percentile FDA days to MDUFA III decision	83	75			
60th Percentile FDA days to MDUFA III decision	88	84			
80th Percentile FDA days to MDUFA III decision	89	87			
Maximum FDA days to MDUFA III decision	179	90			
<b>Average Industry days to MDUFA III decision</b>	50	12			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	14	0			
60th Percentile Industry days to MDUFA III decision	39	1			
80th Percentile Industry days to MDUFA III decision	91	25			
Maximum Industry days to MDUFA III decision	359	53			
<b>Average Total days to MDUFA III decision</b>	125	77			
20th Percentile Total days to MDUFA III decision	73	30			
40th Percentile Total days to MDUFA III decision	96	82			
60th Percentile Total days to MDUFA III decision	125	86			
80th Percentile Total days to MDUFA III decision	174	107			
Maximum Total days to MDUFA III decision	448	136			

**Table 6.6.DAGRID      DAGRID – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	778	241			
Number with MDUFA decision	543	43			
Number of SE decisions	523	42			
Number of NSE decisions	20	1			
Number of Withdrawals	41	0			
Number deleted	57	0			
Rate of SE decisions	96%	98%			
Rate of NSE decisions	4%	2%			
Rate of Withdrawals	5%	0%			
Rate of Deleted	7%	0%			

**Table 6.7.DAGRID      DAGRID – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	12	0			
Mean FDA days for submissions that missed goal	111				
Mean Industry days for submissions that missed goal	101				

**Table 6.1.DCD DCD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	335	206			
Closed before RTA action	0	0			
Number Accepted	151	74			
RTA Review not done and > 15 days since Date Received	9	3			
RTA Review not done and <= 15 days since Date Received	0	12			
Number Not Accepted	175	117			
Rate of submissions not accepted	52%	60%			

\* RTA was not in place 1st quarter, thus Table 6.1.DCD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCD DCD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	429	161			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	386	113			
SI over 60 FDA days	38	8			
SI pending within 60 FDA days	4	39			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	91%	93%			

**Table 6.3.DCD DCD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	424	121			
Average number of FDA days to Substantive Interaction	45	44			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	29	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	43	42			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	50	51			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	57			
Maximum FDA days to Substantive Interaction	98	68			

**Table 6.4.DCD DCD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	453	167			
Non-MDUFA III Decisions	16	0			
MDUFA III Decisions (SE/NSE)	401	67			
MDUFA III Decisions within 90 FDA Days	390	67			
510(k)s pending MDUFA III Decision	36	100			
510(k) pending MDUFA III Decision over 90 FDA days	2	0			
Current Performance Percent within 90 FDA Days	97%	100%			

**Table 6.5.DCD DCD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.3			
Number with MDUFA decision	401	67			
<b>Average FDA days to MDUFA III decision</b>	65	48			
20th Percentile FDA days to MDUFA III decision	31	28			
40th Percentile FDA days to MDUFA III decision	57	30			
60th Percentile FDA days to MDUFA III decision	85	56			
80th Percentile FDA days to MDUFA III decision	89	66			
Maximum FDA days to MDUFA III decision	200	90			
<b>Average Industry days to MDUFA III decision</b>	40	8			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	8	0			
60th Percentile Industry days to MDUFA III decision	33	0			
80th Percentile Industry days to MDUFA III decision	69	18			
Maximum Industry days to MDUFA III decision	358	56			
<b>Average Total days to MDUFA III decision</b>	105	55			
20th Percentile Total days to MDUFA III decision	36	28			
40th Percentile Total days to MDUFA III decision	80	30			
60th Percentile Total days to MDUFA III decision	112	58			
80th Percentile Total days to MDUFA III decision	151	88			
Maximum Total days to MDUFA III decision	447	144			



**Table 6.6.DCD DCD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	453	167			
Number with MDUFA decision	401	67			
Number of SE decisions	392	67			
Number of NSE decisions	9	0			
Number of Withdrawals	9	0			
Number deleted	7	0			
Rate of SE decisions	98%	100%			
Rate of NSE decisions	2%	0%			
Rate of Withdrawals	2%	0%			
Rate of Deleted	2%	0%			

**Table 6.7.DCD DCD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	11	0			
Mean FDA days for submissions that missed goal	118				
Mean Industry days for submissions that missed goal	78				

**Table 6.1.DNPMD      DNPMD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	190	107			
Closed before RTA action	0	1			
Number Accepted	39	34			
RTA Review not done and > 15 days since Date Received	1	4			
RTA Review not done and <= 15 days since Date Received	0	11			
Number Not Accepted	150	57			
Rate of submissions not accepted	79%	60%			

\* RTA was not in place 1st quarter, thus Table 6.1.DNPMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DNPMD      DNPMD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	221	67			
Deleted or withdrawn prior to SI	2	0			
SI within 60 FDA days	192	43			
SI over 60 FDA days	26	4			
SI pending within 60 FDA days	1	20			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	88%	91%			

**Table 6.3.DNPMD      DNPMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	218	47			
Average number of FDA days to Substantive Interaction	52	54			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	43	55			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	55	58			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	59			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	60	60			
Maximum FDA days to Substantive Interaction	80	61			

**Table 6.4.DNPMD      DNPMD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	227	69			
Non-MDUFA III Decisions	20	1			
MDUFA III Decisions (SE/NSE)	162	15			
MDUFA III Decisions within 90 FDA Days	158	15			
510(k)s pending MDUFA III Decision	45	53			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.DNPMD      DNPMD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.9	1.5			
Number with MDUFA decision	162	15			
<b>Average FDA days to MDUFA III decision</b>	82	71			
20th Percentile FDA days to MDUFA III decision	80	48			
40th Percentile FDA days to MDUFA III decision	88	75			
60th Percentile FDA days to MDUFA III decision	89	90			
80th Percentile FDA days to MDUFA III decision	90	90			
Maximum FDA days to MDUFA III decision	148	90			
<b>Average Industry days to MDUFA III decision</b>	61	11			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	29	0			
60th Percentile Industry days to MDUFA III decision	69	7			
80th Percentile Industry days to MDUFA III decision	116	16			
Maximum Industry days to MDUFA III decision	180	52			
<b>Average Total days to MDUFA III decision</b>	143	82			
20th Percentile Total days to MDUFA III decision	89	48			
40th Percentile Total days to MDUFA III decision	112	84			
60th Percentile Total days to MDUFA III decision	155	90			
80th Percentile Total days to MDUFA III decision	202	103			
Maximum Total days to MDUFA III decision	270	142			

**Table 6.6.DNPMD      DNPMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	227	69			
Number with MDUFA decision	162	15			
Number of SE decisions	152	15			
Number of NSE decisions	10	0			
Number of Withdrawals	9	0			
Number deleted	6	0			
Rate of SE decisions	94%	100%			
Rate of NSE decisions	6%	0%			
Rate of Withdrawals	4%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DNPMD      DNPMD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	0			
Mean FDA days for submissions that missed goal	108				
Mean Industry days for submissions that missed goal	70				

**Table 6.1.DOD DOD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	523	302			
Closed before RTA action	0	0			
Number Accepted	181	118			
RTA Review not done and > 15 days since Date Received	0	2			
RTA Review not done and <= 15 days since Date Received	0	14			
Number Not Accepted	342	168			
Rate of submissions not accepted	65%	58%			

\* RTA was not in place 1st quarter, thus Table 6.1.DOD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOD DOD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	654	259			
Deleted or withdrawn prior to SI	3	0			
SI within 60 FDA days	618	178			
SI over 60 FDA days	29	2			
SI pending within 60 FDA days	4	78			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	1			
Current SI Performance Percent within 60 FDA days	96%	98%			

**Table 6.3.DOD DOD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	647	180			
Average number of FDA days to Substantive Interaction	48	46			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	30	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	48	48			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	55			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	58			
Maximum FDA days to Substantive Interaction	88	84			

**Table 6.4.DOD DOD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	655	259			
Non-MDUFA III Decisions	55	1			
MDUFA III Decisions (SE/NSE)	552	107			
MDUFA III Decisions within 90 FDA Days	548	107			
510(k)s pending MDUFA III Decision	48	151			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DOD DOD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.6	1.4			
Number with MDUFA decision	552	107			
<b>Average FDA days to MDUFA III decision</b>	69	59			
20th Percentile FDA days to MDUFA III decision	48	30			
40th Percentile FDA days to MDUFA III decision	71	55			
60th Percentile FDA days to MDUFA III decision	85	63			
80th Percentile FDA days to MDUFA III decision	88	84			
Maximum FDA days to MDUFA III decision	100	90			
<b>Average Industry days to MDUFA III decision</b>	34	8			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	25	0			
80th Percentile Industry days to MDUFA III decision	62	18			
Maximum Industry days to MDUFA III decision	272	64			
<b>Average Total days to MDUFA III decision</b>	103	67			
20th Percentile Total days to MDUFA III decision	50	30			
40th Percentile Total days to MDUFA III decision	82	56			
60th Percentile Total days to MDUFA III decision	105	76			
80th Percentile Total days to MDUFA III decision	148	90			
Maximum Total days to MDUFA III decision	360	143			



**Table 6.6.DOD DOD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	655	259			
Number with MDUFA decision	552	107			
Number of SE decisions	535	106			
Number of NSE decisions	17	1			
Number of Withdrawals	29	1			
Number deleted	25	0			
Rate of SE decisions	97%	99%			
Rate of NSE decisions	3%	1%			
Rate of Withdrawals	4%	0.4%			
Rate of Deleted	4%	0%			

**Table 6.7.DOD DOD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	0			
Mean FDA days for submissions that missed goal	97				
Mean Industry days for submissions that missed goal	104				

**Table 6.1.DOED DOED – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	118	60			
Closed before RTA action	0	0			
Number Accepted	59	30			
RTA Review not done and > 15 days since Date Received	5	1			
RTA Review not done and <= 15 days since Date Received	0	3			
Number Not Accepted	54	26			
Rate of submissions not accepted	46%	46%			

\* RTA was not in place 1st quarter, thus Table 6.1.DOED for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DOED DOED – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	138	47			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	132	38			
SI over 60 FDA days	5	0			
SI pending within 60 FDA days	1	9			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	96%	100%			

**Table 6.3.DOED DOED – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	137	38			
Average number of FDA days to Substantive Interaction	49	49			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	43	44			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	48	51			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	54	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	57	58			
Maximum FDA days to Substantive Interaction	88	60			

**Table 6.4.DOED DOED – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	145	47			
Non-MDUFA III Decisions	17	1			
MDUFA III Decisions (SE/NSE)	111	19			
MDUFA III Decisions within 90 FDA Days	108	19			
510(k)s pending MDUFA III Decision	17	27			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	97%	100%			

**Table 6.5.DOE DOED – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.8	1.6			
Number with MDUFA decision	111	19			
<b>Average FDA days to MDUFA III decision</b>	74	70			
20th Percentile FDA days to MDUFA III decision	54	44			
40th Percentile FDA days to MDUFA III decision	83	80			
60th Percentile FDA days to MDUFA III decision	88	85			
80th Percentile FDA days to MDUFA III decision	89	90			
Maximum FDA days to MDUFA III decision	91	90			
<b>Average Industry days to MDUFA III decision</b>	48	14			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	15	1			
60th Percentile Industry days to MDUFA III decision	40	14			
80th Percentile Industry days to MDUFA III decision	76	27			
Maximum Industry days to MDUFA III decision	185	56			
<b>Average Total days to MDUFA III decision</b>	122	84			
20th Percentile Total days to MDUFA III decision	65	44			
40th Percentile Total days to MDUFA III decision	97	84			
60th Percentile Total days to MDUFA III decision	125	99			
80th Percentile Total days to MDUFA III decision	157	117			
Maximum Total days to MDUFA III decision	274	146			

**Table 6.6.DOED DOED – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	145	47			
Number with MDUFA decision	111	19			
Number of SE decisions	108	19			
Number of NSE decisions	3	0			
Number of Withdrawals	8	0			
Number deleted	8	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	6%	0%			
Rate of Deleted	6%	0%			

**Table 6.7.DOED DOED – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	3	0			
Mean FDA days for submissions that missed goal	91				
Mean Industry days for submissions that missed goal	123				

**Table 6.1.DRGUD      DRGUD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	210	137			
Closed before RTA action	0	2			
Number Accepted	66	63			
RTA Review not done and > 15 days since Date Received	0	4			
RTA Review not done and <= 15 days since Date Received	0	7			
Number Not Accepted	144	61			
Rate of submissions not accepted	69%	48%			

\* RTA was not in place 1st quarter, thus Table 6.1.DRGUD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRGUD      DRGUD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	259	105			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	242	74			
SI over 60 FDA days	9	1			
SI pending within 60 FDA days	5	29			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	2	1			
Current SI Performance Percent within 60 FDA days	96%	97%			

**Table 6.3.DRGUD      DRGUD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	251	75			
Average number of FDA days to Substantive Interaction	48	46			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	35	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	49	46			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	55	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	58	59			
Maximum FDA days to Substantive Interaction	73	84			

**Table 6.4.DRGUD      DRGUD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	272	109			
Non-MDUFA III Decisions	29	2			
MDUFA III Decisions (SE/NSE)	201	33			
MDUFA III Decisions within 90 FDA Days	201	33			
510(k)s pending MDUFA III Decision	42	74			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 6.5.DRGUD      DRGUD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.8	1.5			
Number with MDUFA decision	201	33			
<b>Average FDA days to MDUFA III decision</b>	69	49			
20th Percentile FDA days to MDUFA III decision	45	26			
40th Percentile FDA days to MDUFA III decision	75	30			
60th Percentile FDA days to MDUFA III decision	84	53			
80th Percentile FDA days to MDUFA III decision	88	82			
Maximum FDA days to MDUFA III decision	90	90			
<b>Average Industry days to MDUFA III decision</b>	59	9			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	24	0			
60th Percentile Industry days to MDUFA III decision	55	5			
80th Percentile Industry days to MDUFA III decision	114	21			
Maximum Industry days to MDUFA III decision	356	62			
<b>Average Total days to MDUFA III decision</b>	128	59			
20th Percentile Total days to MDUFA III decision	56	27			
40th Percentile Total days to MDUFA III decision	103	40			
60th Percentile Total days to MDUFA III decision	129	63			
80th Percentile Total days to MDUFA III decision	192	91			
Maximum Total days to MDUFA III decision	445	149			



**Table 6.6.DRGUD      DRGUD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	272	109			
Number with MDUFA decision	201	33			
Number of SE decisions	188	32			
Number of NSE decisions	13	1			
Number of Withdrawals	15	0			
Number deleted	12	0			
Rate of SE decisions	94%	97%			
Rate of NSE decisions	6%	3%			
Rate of Withdrawals	6%	0%			
Rate of Deleted	4%	0%			

**Table 6.7.DRGUD      DRGUD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DSD DSD – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	375	219			
Closed before RTA action	3	0			
Number Accepted	136	79			
RTA Review not done and > 15 days since Date Received	3	2			
RTA Review not done and <= 15 days since Date Received	0	10			
Number Not Accepted	233	128			
Rate of submissions not accepted	63%	61%			

\* RTA was not in place 1st quarter, thus Table 6.1.DSD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DSD DSD – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	469	149			
Deleted or withdrawn prior to SI	3	0			
SI within 60 FDA days	413	87			
SI over 60 FDA days	44	14			
SI pending within 60 FDA days	8	48			
SI pending over 60 FDA days	1	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	90%	86%			

**Table 6.3.DSD DSD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	457	101			
Average number of FDA days to Substantive Interaction	45	48			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	27	28			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	44	45			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	59			
Maximum FDA days to Substantive Interaction	90	90			

**Table 6.4.DSD DSD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	477	153			
Non-MDUFA III Decisions	61	1			
MDUFA III Decisions (SE/NSE)	347	51			
MDUFA III Decisions within 90 FDA Days	341	51			
510(k)s pending MDUFA III Decision	69	101			
510(k) pending MDUFA III Decision over 90 FDA days	1	0			
Current Performance Percent within 90 FDA Days	98%	100%			

**Table 6.5.DSD DSD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.3			
Number with MDUFA decision	347	51			
<b>Average FDA days to MDUFA III decision</b>	66	52			
20th Percentile FDA days to MDUFA III decision	38	28			
40th Percentile FDA days to MDUFA III decision	62	45			
60th Percentile FDA days to MDUFA III decision	84	59			
80th Percentile FDA days to MDUFA III decision	88	76			
Maximum FDA days to MDUFA III decision	150	90			
<b>Average Industry days to MDUFA III decision</b>	49	8			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	14	0			
60th Percentile Industry days to MDUFA III decision	33	0			
80th Percentile Industry days to MDUFA III decision	91	24			
Maximum Industry days to MDUFA III decision	370	43			
<b>Average Total days to MDUFA III decision</b>	114	60			
20th Percentile Total days to MDUFA III decision	44	28			
40th Percentile Total days to MDUFA III decision	87	48			
60th Percentile Total days to MDUFA III decision	115	61			
80th Percentile Total days to MDUFA III decision	173	90			
Maximum Total days to MDUFA III decision	508	133			

**Table 6.6.DSD DSD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	477	153			
Number with MDUFA decision	347	51			
Number of SE decisions	335	51			
Number of NSE decisions	12	0			
Number of Withdrawals	33	0			
Number deleted	23	0			
Rate of SE decisions	97%	100%			
Rate of NSE decisions	3%	0%			
Rate of Withdrawals	7%	0%			
Rate of Deleted	5%	0%			

**Table 6.7.DSD DSD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	6	0			
Mean FDA days for submissions that missed goal	113				
Mean Industry days for submissions that missed goal	154				

**Table 6.1.DCTD DCTD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	188	93			
Closed before RTA action	1	0			
Number Accepted	118	58			
RTA Review not done and > 15 days since Date Received	0	1			
RTA Review not done and <= 15 days since Date Received	0	5			
Number Not Accepted	69	29			
Rate of submissions not accepted	37%	33%			

\* RTA was not in place 1st quarter, thus Table 6.1.DCTD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DCTD DCTD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	246	73			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	244	57			
SI over 60 FDA days	0	0			
SI pending within 60 FDA days	2	16			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	100%	100%			

**Table 6.3.DCTD DCTD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	244	57			
Average number of FDA days to Substantive Interaction	41	40			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	29	29			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	38	32			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	45	46			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	52	54			
Maximum FDA days to Substantive Interaction	60	59			

**Table 6.4.DCTD DCTD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	246	73			
Non-MDUFA III Decisions	20	0			
MDUFA III Decisions (SE/NSE)	190	25			
MDUFA III Decisions within 90 FDA Days	189	25			
510(k)s pending MDUFA III Decision	36	48			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	99%	100%			

**Table 6.5.DCTD DCTD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.7	1.3			
Number with MDUFA decision	190	25			
<b>Average FDA days to MDUFA III decision</b>	62	48			
20th Percentile FDA days to MDUFA III decision	32	29			
40th Percentile FDA days to MDUFA III decision	53	32			
60th Percentile FDA days to MDUFA III decision	81	49			
80th Percentile FDA days to MDUFA III decision	87	63			
Maximum FDA days to MDUFA III decision	99	89			
<b>Average Industry days to MDUFA III decision</b>	59	9			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	52	0			
80th Percentile Industry days to MDUFA III decision	118	21			
Maximum Industry days to MDUFA III decision	343	61			
<b>Average Total days to MDUFA III decision</b>	121	57			
20th Percentile Total days to MDUFA III decision	32	29			
40th Percentile Total days to MDUFA III decision	72	32			
60th Percentile Total days to MDUFA III decision	131	59			
80th Percentile Total days to MDUFA III decision	202	90			
Maximum Total days to MDUFA III decision	429	149			



**Table 6.6.DCTD DCTD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	246	73			
Number with MDUFA decision	190	25			
Number of SE decisions	186	24			
Number of NSE decisions	4	1			
Number of Withdrawals	12	0			
Number deleted	8	0			
Rate of SE decisions	98%	96%			
Rate of NSE decisions	2%	4%			
Rate of Withdrawals	5%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DCTD DCTD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	1	0			
Mean FDA days for submissions that missed goal	99				
Mean Industry days for submissions that missed goal	193				

**Table 6.1.DIHD DIHD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	73	38			
Closed before RTA action	1	0			
Number Accepted	52	22			
RTA Review not done and > 15 days since Date Received	3	0			
RTA Review not done and <= 15 days since Date Received	0	4			
Number Not Accepted	17	12			
Rate of submissions not accepted	24%	35%			

\* RTA was not in place 1st quarter, thus Table 6.1.DIHD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DIHD DIHD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	87	25			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	85	16			
SI over 60 FDA days	1	0			
SI pending within 60 FDA days	1	9			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	99%	100%			

**Table 6.3.DIHD DIHD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	86	16			
Average number of FDA days to Substantive Interaction	48	46			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	41	44			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	50	46			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	53			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	57			
Maximum FDA days to Substantive Interaction	63	60			

**Table 6.4.DIHD DIHD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	87	25			
Non-MDUFA III Decisions	20	0			
MDUFA III Decisions (SE/NSE)	52	4			
MDUFA III Decisions within 90 FDA Days	52	4			
510(k)s pending MDUFA III Decision	15	21			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 6.5.DIHD DIHD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	2.0	1.3			
Number with MDUFA decision	52	4			
<b>Average FDA days to MDUFA III decision</b>	72	51			
20th Percentile FDA days to MDUFA III decision	50	34			
40th Percentile FDA days to MDUFA III decision	76	44			
60th Percentile FDA days to MDUFA III decision	86	58			
80th Percentile FDA days to MDUFA III decision	88	68			
Maximum FDA days to MDUFA III decision	90	77			
<b>Average Industry days to MDUFA III decision</b>	105	18			
20th Percentile Industry days to MDUFA III decision	5	0			
40th Percentile Industry days to MDUFA III decision	72	0			
60th Percentile Industry days to MDUFA III decision	149	0			
80th Percentile Industry days to MDUFA III decision	174	28			
Maximum Industry days to MDUFA III decision	329	70			
<b>Average Total days to MDUFA III decision</b>	178	68			
20th Percentile Total days to MDUFA III decision	81	47			
40th Percentile Total days to MDUFA III decision	147	65			
60th Percentile Total days to MDUFA III decision	229	74			
80th Percentile Total days to MDUFA III decision	259	90			
Maximum Total days to MDUFA III decision	417	110			

**Table 6.6.DIHD DIHD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	87	25			
Number with MDUFA decision	52	4			
Number of SE decisions	46	4			
Number of NSE decisions	6	0			
Number of Withdrawals	4	0			
Number deleted	14	0			
Rate of SE decisions	88%	100%			
Rate of NSE decisions	12%	0%			
Rate of Withdrawals	5%	0%			
Rate of Deleted	16%	0%			

**Table 6.7.DIHD DIHD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DMD DMD – 510(k) Acceptance Review Decision**

<b>Performance Metric</b>	<b>FY 2013*</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number Received	59	38			
Closed before RTA action	0	0			
Number Accepted	55	37			
RTA Review not done and > 15 days since Date Received	0	0			
RTA Review not done and <= 15 days since Date Received	0	0			
Number Not Accepted	4	1			
Rate of submissions not accepted	7%	3%			

\* RTA was not in place 1st quarter, thus Table 6.1.DMD for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DMD DMD – 510(k) Substantive Interaction Performance Goals**

<b>Substantive Interaction (SI) Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	80	37			
Deleted or withdrawn prior to SI	0	0			
SI within 60 FDA days	79	25			
SI over 60 FDA days	1	0			
SI pending within 60 FDA days	0	12			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	99%	100%			

**Table 6.3.DMD DMD – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of Substantive Interactions	80	25			
Average number of FDA days to Substantive Interaction	43	43			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	28	28			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	39	34			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	53	51			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	57	59			
Maximum FDA days to Substantive Interaction	61	60			

**Table 6.4.DMD DMD – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	91% within 90 FDA days	93% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
510(k)s accepted	80	37			
Non-MDUFA III Decisions	7	0			
MDUFA III Decisions (SE/NSE)	71	15			
MDUFA III Decisions within 90 FDA Days	71	15			
510(k)s pending MDUFA III Decision	2	22			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100%	100%			

**Table 6.5.DMD DMD – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.3	1.1			
Number with MDUFA decision	71	15			
<b>Average FDA days to MDUFA III decision</b>	58	47			
20th Percentile FDA days to MDUFA III decision	29	28			
40th Percentile FDA days to MDUFA III decision	55	29			
60th Percentile FDA days to MDUFA III decision	78	40			
80th Percentile FDA days to MDUFA III decision	81	77			
Maximum FDA days to MDUFA III decision	89	90			
<b>Average Industry days to MDUFA III decision</b>	32	6			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	65	0			
Maximum Industry days to MDUFA III decision	180	65			
<b>Average Total days to MDUFA III decision</b>	90	52			
20th Percentile Total days to MDUFA III decision	29	28			
40th Percentile Total days to MDUFA III decision	58	29			
60th Percentile Total days to MDUFA III decision	81	52			
80th Percentile Total days to MDUFA III decision	133	85			
Maximum Total days to MDUFA III decision	267	112			



**Table 6.6.DMD DMD – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	80	37			
Number with MDUFA decision	71	15			
Number of SE decisions	71	13			
Number of NSE decisions	0	2			
Number of Withdrawals	5	0			
Number deleted	2	0			
Rate of SE decisions	100%	87%			
Rate of NSE decisions	0.0%	13%			
Rate of Withdrawals	6%	0%			
Rate of Deleted	3%	0%			

**Table 6.7.DMD DMD – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal					
Mean Industry days for submissions that missed goal					

**Table 6.1.DRH DRH – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013*	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	256	165			
Closed before RTA action	0	0			
Number Accepted	151	92			
RTA Review not done and > 15 days since Date Received	15	3			
RTA Review not done and <= 15 days since Date Received	0	8			
Number Not Accepted	90	62			
Rate of submissions not accepted	35%	39%			

\* RTA was not in place 1st quarter, thus Table 6.1.DRH for FY2013 includes only 510(k)s received on or after January 1, 2013. All other tables include 510(k)s received on or after October 1, 2012.

**Table 6.2.DRH DRH – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA Days	85% SI within 60 FDA Days	95% SI within 60 FDA Days	95% SI within 60 FDA Days
Eligible for SI	347	136			
Deleted or withdrawn prior to SI	1	0			
SI within 60 FDA days	303	106			
SI over 60 FDA days	41	5			
SI pending within 60 FDA days	2	25			
SI pending over 60 FDA days	0	0			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	88%	95%			

**Table 6.3.DRH DRH – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	344	111			
Average number of FDA days to Substantive Interaction	47	47			
20 <sup>th</sup> Percentile FDA days to Substantive Interaction	31	30			
40 <sup>th</sup> Percentile FDA days to Substantive Interaction	44	46			
60 <sup>th</sup> Percentile FDA days to Substantive Interaction	56	56			
80 <sup>th</sup> Percentile FDA days to Substantive Interaction	59	59			
Maximum FDA days to Substantive Interaction	91	93			

**Table 6.4.DRH DRH – 510(k) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013 91% within 90 FDA days	FY 2014 93% within 90 FDA days	FY 2015 95% within 90 FDA days	FY 2016 95% within 90 FDA days	FY 2017 95% within 90 FDA days
510(k)s accepted	401	152			
Non-MDUFA III Decisions	10	1			
MDUFA III Decisions (SE/NSE)	367	76			
MDUFA III Decisions within 90 FDA Days	363	72			
510(k)s pending MDUFA III Decision	24	75			
510(k) pending MDUFA III Decision over 90 FDA days	0	1			
Current Performance Percent within 90 FDA Days	99%	94%			

**Table 6.5.DRH DRH – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.6	1.4			
Number with MDUFA decision	367	76			
<b>Average FDA days to MDUFA III decision</b>	61	56			
20th Percentile FDA days to MDUFA III decision	33	30			
40th Percentile FDA days to MDUFA III decision	55	46			
60th Percentile FDA days to MDUFA III decision	76	59			
80th Percentile FDA days to MDUFA III decision	87	85			
Maximum FDA days to MDUFA III decision	121	137			
<b>Average Industry days to MDUFA III decision</b>	30	11			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	18	0			
80th Percentile Industry days to MDUFA III decision	51	24			
Maximum Industry days to MDUFA III decision	357	80			
<b>Average Total days to MDUFA III decision</b>	91	67			
20th Percentile Total days to MDUFA III decision	36	30			
40th Percentile Total days to MDUFA III decision	68	49			
60th Percentile Total days to MDUFA III decision	89	74			
80th Percentile Total days to MDUFA III decision	129	93			
Maximum Total days to MDUFA III decision	447	138			

**Table 6.6.DRH DRH – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	401	152			
Number with MDUFA decision	367	76			
Number of SE decisions	359	75			
Number of NSE decisions	8	1			
Number of Withdrawals	8	1			
Number deleted	2	0			
Rate of SE decisions	98%	99%			
Rate of NSE decisions	2%	1%			
Rate of Withdrawals	2%	0.7%			
Rate of Deleted	0%	0%			

**Table 6.7.DRH DRH – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	4	4			
Mean FDA days for submissions that missed goal	105	106			
Mean Industry days for submissions that missed goal	75	2			

## **Section 7 510(k) Annual General Metrics**

510(k) Annual Metrics and Goals will be reported in the Annual Report.

## **Section 8 Annual Metrics for De Novo Requests**

Pre De Novo Annual Metrics and Goals will be reported in the Annual Report.

## **Section 9 Pre-Submissions**



## Pre-Submissions – Center Level

**Table 9.1 CDRH – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	1770	867			
Number requesting a meeting or teleconference	967	481			
Number with meetings or teleconferences held	752	244			
Average days to meeting	59	59			
20 <sup>th</sup> Percentile days to meeting	38	40			
40 <sup>th</sup> Percentile days to meeting	55	57			
60 <sup>th</sup> Percentile days to meeting	66	68			
80 <sup>th</sup> Percentile days to meeting	77	74			
Maximum days to meeting	183	158			

## Pre-Submissions – Office Level

**Table 9.1.ODE ODE – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	975	519			
Number requesting a meeting or teleconference	608	319			
Number with meetings or teleconferences held	453	157			
Average days to meeting	62	63			
20 <sup>th</sup> Percentile days to meeting	40	46			
40 <sup>th</sup> Percentile days to meeting	57	60			
60 <sup>th</sup> Percentile days to meeting	67	69			
80 <sup>th</sup> Percentile days to meeting	79	78			
Maximum days to meeting	183	158			

**Table 9.1.OIR OIR – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	795	348			
Number requesting a meeting or teleconference	359	162			
Number with meetings or teleconferences held	299	87			
Average days to meeting	55	54			
20 <sup>th</sup> Percentile days to meeting	37	38			
40 <sup>th</sup> Percentile days to meeting	52	52			
60 <sup>th</sup> Percentile days to meeting	63	64			
80 <sup>th</sup> Percentile days to meeting	71	71			
Maximum days to meeting	138	115			

## Pre-Submissions – Division Level

**Table 9.1.DAGRID      DAGRID – Pre-Submissions Performance Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	154	95			
Number requesting a meeting or teleconference	80	47			
Number with meetings or teleconferences held	57	24			
Average days to meeting	68	65			
20 <sup>th</sup> Percentile days to meeting	52	54			
40 <sup>th</sup> Percentile days to meeting	65	61			
60 <sup>th</sup> Percentile days to meeting	75	72			
80 <sup>th</sup> Percentile days to meeting	83	82			
Maximum days to meeting	121	95			

**Table 9.1.DCD DCD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	307	170			
Number requesting a meeting or teleconference	214	111			
Number with meetings or teleconferences held	173	62			
Average days to meeting	56	55			
20 <sup>th</sup> Percentile days to meeting	35	39			
40 <sup>th</sup> Percentile days to meeting	49	53			
60 <sup>th</sup> Percentile days to meeting	62	60			
80 <sup>th</sup> Percentile days to meeting	74	69			
Maximum days to meeting	134	103			

**Table 9.1.DNPMD      DNPMD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	78	48			
Number requesting a meeting or teleconference	50	33			
Number with meetings or teleconferences held	32	9			
Average days to meeting	70	75			
20 <sup>th</sup> Percentile days to meeting	48	62			
40 <sup>th</sup> Percentile days to meeting	63	74			
60 <sup>th</sup> Percentile days to meeting	77	78			
80 <sup>th</sup> Percentile days to meeting	91	88			
Maximum days to meeting	163	120			

**Table 9.1.DOD DOD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	98	55			
Number requesting a meeting or teleconference	61	41			
Number with meetings or teleconferences held	39	20			
Average days to meeting	61	73			
20 <sup>th</sup> Percentile days to meeting	45	60			
40 <sup>th</sup> Percentile days to meeting	57	72			
60 <sup>th</sup> Percentile days to meeting	69	74			
80 <sup>th</sup> Percentile days to meeting	77	82			
Maximum days to meeting	129	158			

**Table 9.1.DOED DOED – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	87	33			
Number requesting a meeting or teleconference	49	21			
Number with meetings or teleconferences held	35	11			
Average days to meeting	66	73			
20 <sup>th</sup> Percentile days to meeting	53	66			
40 <sup>th</sup> Percentile days to meeting	64	69			
60 <sup>th</sup> Percentile days to meeting	70	70			
80 <sup>th</sup> Percentile days to meeting	83	92			
Maximum days to meeting	118	114			



**Table 9.1.DRGUD      DRGUD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	128	64			
Number requesting a meeting or teleconference	75	41			
Number with meetings or teleconferences held	60	22			
Average days to meeting	60	55			
20 <sup>th</sup> Percentile days to meeting	47	28			
40 <sup>th</sup> Percentile days to meeting	60	51			
60 <sup>th</sup> Percentile days to meeting	67	67			
80 <sup>th</sup> Percentile days to meeting	71	75			
Maximum days to meeting	132	98			

**Table 9.1.DSD DSD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	123	56			
Number requesting a meeting or teleconference	79	25			
Number with meetings or teleconferences held	57	9			
Average days to meeting	68	76			
20 <sup>th</sup> Percentile days to meeting	41	63			
40 <sup>th</sup> Percentile days to meeting	64	73			
60 <sup>th</sup> Percentile days to meeting	74	73			
80 <sup>th</sup> Percentile days to meeting	86	88			
Maximum days to meeting	183	98			

**Table 9.1.DCTD DCTD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	217	71			
Number requesting a meeting or teleconference	106	33			
Number with meetings or teleconferences held	90	19			
Average days to meeting	51	48			
20 <sup>th</sup> Percentile days to meeting	36	36			
40 <sup>th</sup> Percentile days to meeting	49	41			
60 <sup>th</sup> Percentile days to meeting	59	48			
80 <sup>th</sup> Percentile days to meeting	68	56			
Maximum days to meeting	90	77			

**Table 9.1.DIHD DIHD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	276	144			
Number requesting a meeting or teleconference	150	82			
Number with meetings or teleconferences held	125	47			
Average days to meeting	62	57			
20 <sup>th</sup> Percentile days to meeting	42	38			
40 <sup>th</sup> Percentile days to meeting	58	60			
60 <sup>th</sup> Percentile days to meeting	69	68			
80 <sup>th</sup> Percentile days to meeting	83	73			
Maximum days to meeting	138	115			

**Table 9.1.DMD DMD – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	232	108			
Number requesting a meeting or teleconference	58	27			
Number with meetings or teleconferences held	48	10			
Average days to meeting	52	58			
20 <sup>th</sup> Percentile days to meeting	42	46			
40 <sup>th</sup> Percentile days to meeting	51	52			
60 <sup>th</sup> Percentile days to meeting	60	60			
80 <sup>th</sup> Percentile days to meeting	66	71			
Maximum days to meeting	81	79			

**Table 9.1.DRH DRH – Pre-Submissions Performance Metrics**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number of all qualified Pre-Submissions received	70	25			
Number requesting a meeting or teleconference	45	20			
Number with meetings or teleconferences held	36	12			
Average days to meeting	47	50			
20 <sup>th</sup> Percentile days to meeting	31	25			
40 <sup>th</sup> Percentile days to meeting	43	50			
60 <sup>th</sup> Percentile days to meeting	57	65			
80 <sup>th</sup> Percentile days to meeting	63	70			
Maximum days to meeting	98	78			

## **Section 10      CLIA Waiver Annual Metrics**

CLIA Waiver Annual Metrics and Goals will be reported in the Annual Report.

## **Section 11      Investigational Device Exemptions (IDEs)**



## IDEs – Center Level

Table 11.1 CDRH - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	120			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.2			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2			

## IDEs – Office Level

Table 11.1.ODE ODE - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	88			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.2			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.2			

Table 11.1.OIR OIR - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	32			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.1			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1			

## IDEs – Division Level

Table 11.1.DAGRID DAGRID - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	3			
Average number of cycles to approval to or conditional approval of the IDE	N/A	n/a			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	n/a			

Table 11.1.DCD DCD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	23			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.3			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3			

Table 11.1.DNPMD DNPMD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	23			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.1			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.1			

Table 11.1.DOD DOD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	4			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DOED DOED - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	13			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DRGUD DRGUD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	13			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.3			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.3			

Table 11.1.DSD DSD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	9			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DCTD DCTD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	14			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DIHD DIHD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	13			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DMD DMD - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	1			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.0			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.0			

Table 11.1.DRH DRH - IDE Performance Metrics

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of IDEs received	N/A	4			
Average number of cycles to approval to or conditional approval of the IDE	N/A	1.7			
Average number of amendments prior to approval or conditional approval of the IDE	N/A	0.7			

## Appendix A Variable Definitions

### Section 1 PMA Originals and Panel Track Supplements

**Table 1.1 and Tables 1.1.x PMA Original and Panel Track Supplements – Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number with accepted RTA review	Number Received (line 1) that got "RTA Accepted" (RTAA) or RTAX decision in the first RTA review cycle entered by reviewer.
4	Number without RTA Review and > 15 Days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	Number without RTA Review and <= 15 Days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted for Filing Review	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" (RTA1) decision in the first RTA review cycle.
7	Rate of submissions not accepted for filing review	Number Not Accepted for Filing Review (line 6) divided by the total of Number Accepted (line 3), Number without RTA Review and > 15 Days since Date Received (line 4), and Number Not Accepted for Filing Review (line 6).

**Table 1.2 and Tables 1.2.x PMA Original and Panel Track Supplements – Filing Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Originals and Panel Track Supplements received in this fiscal year (see definition for the Received cohort above).
2	Number Accepted <sup>#</sup>	Number Received (line 1) that got "RTA Accepted" (RTAA), RTAX, or RTAN decision in the first RTA review cycle entered by reviewer.
3	Number with completed RTF	Number of submissions with the first RTF review completed in this fiscal year.
4	Number Not Filed	Number of submissions with completed RTF (line 3) that got the NOFI decision in the first RTF review.
5	Rate of submissions Not Filed	Number Not Filed (line 4) divided by Number with completed RTF (line 3).

<sup>#</sup> Number accepted includes PMA Original and Panel Track Supplements that received a RTAA, RTAX, or RTAN decision for FY 2013

**Table 1.3 and Tables 1.3.x****PMA Originals & Panel Track Supplements Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year.
2	SI Goal Met	Number of submissions with SI action within goal.
3	SI Goal Not Met	Number of submissions with SI action taken past goal.
4	SI Pending Within Goal	Number of submissions that are under review with no SI within goal.
5	SI Pending Past Goal	Number of submissions that are under with no SI past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or final decision that does not qualify as SI and that did not have an SI prior to that decision (i.e., converted and withdrawn).
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 1.4 and Tables 1.4.x****PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of PMA Originals and Panel Track Supplements filed in this fiscal year that had an SI.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all PMA Originals and Panel Track Supplements with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 1.5 and Tables 1.5.x****PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and did not have Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.6 and Tables 1.6.x****PMA Originals & Panel Track Supplements (with Panel Review) MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	Number of PMAs filed	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, and had a Panel review requested.
2	Non-MDUFA III Decisions	Submissions filed (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, XPMA).
3	MDUFA III Decisions	Submissions filed (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	PMAs pending MDUFA III Decision	Number of submissions filed in this fiscal year (line 1) which do not have a MDUFA III decision or final decision.
6	PMAs pending MDUFA III Decision Past Goal	Number of submissions pending MDUFA III Decision (line 5) past goal. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of submissions with MDUFA III Decisions made on time (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 1.7 and Tables 1.7.x****PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, did not have Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



**Table 1.8 and Tables 1.8.x****PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA III Decision	Number of PMA Original submissions and Panel Track supplements that were filed in this fiscal year, had Panel review requested, and had a MDUFA decision made before or on the report cutoff date.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 1.9 and Tables 1.9.x****PMA Originals and Panel Track Supplements (without Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and did not have Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

**Table 1.10 and Tables 1.10.x****PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable - Definitions**

#	Measure	Description
1	Number Filed	Number of PMA Originals and Panel Track Supplements that were filed in this fiscal year, and had Panel Review requested.
2	Number with MDUFA decision	Number submissions filed (line 1) that also had a MDUFA decision.
3	Number of Withdrawals	Number of submissions filed (line 1) with MDUFA decision of WTDR (Withdrawn).
4	Number of Not Approvable	Number of submissions filed (line 1) with MDUFA decision of NOAP (Not Approvable).
5	Rate of Withdrawals	Number of Withdrawals (line 3) divided by Number with MDUFA decision (line 2).
6	Rate of Not Approvable	Number of Not Approvable (line 4) divided by Number with MDUFA decision (line2).

**Table 1.11 and Tables 1.11.x****PMA Original and Panel Track Supplements (without Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, without Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

**Table 1.12 and Tables 1.12.x****PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of PMA Originals and Panel Track Supplements, filed in this fiscal year, with Panel Review, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

## Section 2 PMA 180 Day Supplements

**Table 2.1 and Tables 2.1.x** PMA 180 Day Supplements Substantive Interaction Goals - Definitions

#	Measure	Description
1	Eligible for SI	Number of 180 day PMA supplements received in this fiscal year. See definition of the received cohort above.
2	SI Goal Met	Number of submissions with an SI action taken within goal.
3	SI Goal Not Met	Number of submissions with an SI action taken past goal.
4	SI Pending Within Goal	Submissions that are under review within goal.
5	SI Pending Past Goal	Submissions that are under review past goal.
6	Closed without SI	Number of submissions that are closed with a MDUFA or NON-MDUFA decision but without an SI.
7	Current SI Performance Percent Goal Met	Number of submissions with SI within goal (line 2) divided by the total number of submissions that either had an SI (line 2 and line 3) or did not have an SI but failed the SI goal (line 5).

**Table 2.2 and Tables 2.2.x** PMA 180 Day Supplements MDUFA Decision Performance Goals - Definitions

#	Measure	Description
1	Supplements filed	Number of 180 day PMA supplements received in this fiscal year.
2	Non-MDUFA III Decisions	Supplements received (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPM).
3	MDUFA III Decisions	Supplements received (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) made before or on the MDUFA goal due date. See General Rules section above for MDUFA goal definition.
5	Supplements pending MDUFA III Decision	Number of supplements received (line 1) that do not have a MDUFA III decision or a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 2.3 and Tables 2.3.x** PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable - Definitions

#	Measure	Description
1	Number Received	Number of PMA 180 Day Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line2).

**Table 2.4 and Tables 2.4.x****PMA 180 Day Supplements Performance Metrics –  
Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 180 Day supplements, received in this fiscal year, with number FDA days to MDUFA III decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

## Section 3 PMA Real Time Supplements

**Table 3.1 and Tables 3.1.x Real Time PMA Supplements MDUFA Performance Goals – Definitions**

#	Measure	Description
1	Supplements received	Number of Real Time PMA supplements that were received in this fiscal year. See the Received cohort definition above.
2	Non-MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a non-MDUFA III decision (such as ABND, CONV, OTHR, RECL, WTDR, XPMA).
3	MDUFA III Decisions	Supplements received in this fiscal year (line 1) and closed with a MDUFA III decision.
4	MDUFA III Decisions Goal Met	Submissions with MDUFA III decisions (line 3) within goal.
5	Supplements pending MDUFA III Decision	Number of supplements received in this fiscal year (line 1) that do not have a MDUFA III decision and are not closed with a final decision.
6	Supplements pending MDUFA III Decision Past Goal	Number of supplements pending MDUFA III Decision (line 5) past goal. These supplements already failed the MDUFA III review goal.
7	Current Performance Percent Goal Met	Number of supplements with MDUFA III Decisions made on time (line 4) divided by the total number of supplements with MDUFA III Decisions (line 3) and pending supplements that already failed the MDUFA goal (line 6).

**Table 3.2 and Tables 3.2.x Real Time PMA Supplements Performance Metrics – Rate of Not Approvable - Definitions**

#	Measure	Description
1	Number Received	Number of PMA Real Time Supplements received in this fiscal year.
2	Number with MDUFA decision	Number supplements received (line 1) and closed with a MDUFA decision.
3	Number of Not Approvable	Number of supplements received (line 1) and closed with MDUFA decision of NOAP (Not Approvable).
4	Rate of Not Approvable	Number of Not Approvable (line 3) divided by Number with MDUFA decision (line 2).

**Table 3.3 and Tables 3.3.x Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of Real Time Supplements, received in this fiscal year, that also have a MDUFA decision, with number of FDA days to MDUFA decision exceeding number of goal days.
2	Mean FDA days for submissions that missed goal	Mean FDA days for supplements that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for supplements that missed the goal (line 1).

## Section 5 PMA Annual Metrics and Goals

**Table 5.1 PMAs (All Review Tracks) Annual General Metrics – Definitions**

#	Measure	Description
1	Premarket Report Submissions	Number of PMA Original submissions, with Reprocessed flag set to "Yes", received in this fiscal year.
2	Original PMAs (Panel) – Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
3	Original PMAs (No Panel) – Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
4	Original PMAs (Panel) – Non-Priority	Number of PMA Original submissions with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
5	Original PMAs (No Panel) – Non-Priority	Number of PMA Original submissions with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
6	Panel Track Supplements (Panel) – Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "Yes", received in this fiscal year.
7	Panel Track Supplements (No Panel) – Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "Yes", received in this fiscal year.
8	Panel Track Supplements (Panel) – Non-Priority	Number of PMA Panel Track Supplements with Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
9	Panel Track Supplements (No Panel) – Non-Priority	Number of PMA Panel Track Supplements with no Panel review requested and Priority flag set to "No" or not set (blank), received in this fiscal year.
10	PMA Modules	Number of PMA Modules received with a valid eCopy or taken off eCopy hold in this fiscal year.
11	180-Day Supplements	Number of PMA 180-Day supplements received in this fiscal year.
12	Real-Time Supplements	Number of PMA Real-Time supplements received in this fiscal year.

**Table 5.2 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Definitions**

#	Measure	Description
1	Number Filed	Total number of PMA Original and Panel Track Supplement submissions filed in this fiscal year.
2	Number with a decision (MDUFA or Non-MDUFA)	Number of submissions filed in this fiscal year (line 1) that were closed with either MDUFA or non-MDUFA decision.
3	% of FY closed	Number with a decision (line 2) divided by Number Filed (line 1).

**Table 5.3 PMA Originals and Panel Track Supplements Annual Shared Outcome Goal – Three-year Rolling Average Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision.
2	Number with MDUFA decision after trimming the upper and lower 5%	Number of PMA submissions filed in this and two previous years that were closed with a MDUFA decision (line 1) excluding 5% of submissions with the lowest number of Total Days to MDUFA III decision and 5% of submissions with the highest number of Total Days to MDUFA III decision.
3	Three-year Rolling Average Total Time to MDUFA decision	Average Total Time (FDA and Industry) for the three-year receipt cohort. Each of the three years has to be closed (95% of submissions must have a MDUFA decision) in order for this value to be calculated. If any of these three years is not closed, then this cell shall be left blank. The rolling average shall be calculated for submissions with MDUFA decision, excluding outliers (top and bottom 5%) – these submissions are counted on line 2. For FY20111 and FY2012 Total Time to MDUFA II (two) decision will be used.

## Section 6 510(k) MDUFA III Performance

**Table 6.1 and Tables 6.1.x 510(k) Acceptance Review Decision - Definitions**

#	Measure	Description
1	Number Received	Number of 510(k) submissions received in this fiscal year. See definition for received cohort above. Third party reviews shall be excluded from this table.
2	Closed before RTA action	Number Received (line 1) that were closed with a final decision before RTA action.
3	Number Accepted	Number Received (line 1) that got "RTA Accepted" (RTAA) decision in the first RTA review cycle entered by reviewer.
4	RTA Review not done and > 15 days since Date Received	Number Received (line 1) that got "Did not perform RTA" (RTAN or RTAS) decision in the first RTA review cycle automatically recorded by CTS at the end of day 15 of RTA review. These RTA reviews deemed approved.
5	RTA Review not done and <= 15 days since Date Received	Number Received (line 1) that are still in the first RTA review cycle.
6	Number Not Accepted	Number of submissions received in this fiscal year (line 1) that got a "Refuse to accept" decision in the first RTA review cycle.
7	Rate of submissions not accepted	Number Not Accepted (line 6) divided by the total of Number Accepted (line 3), Number of RTA Review not done and > 15 days since Date Received (line 4), and Number Not Accepted (line 6).

**Table 6.2 and Tables 6.2.x 510(k) Substantive Interaction Performance Goals - Definitions**

#	Measure	Description
1	Eligible for SI	Number of 510(k) submissions with RTA review accepted in this fiscal year (RTAA, RTAX, RTAN, or RTAS.). Third party 510(k) submissions are excluded from SI performance report.
2	510(k) withdrawn or deleted prior to SI	Number of 510(k)s that were Eligible for SI (line 1) but with the following Non-MDUFA decisions made before or on the cutoff date and before any SI action: WD, DD, DE, HD, K4, NR, RC, RD .
3	SI within 60 FDA days	Number of submissions with SI action within 60 FDA days.
4	SI over 60 FDA days	Number of submissions with SI action taken in more than 60 FDA days.
5	SI pending within 60 FDA days	Submissions that are under review for not more than 60 FDA days and that do not have an SI.
6	SI pending over 60 FDA days	Submissions that are under review over 60 FDA days and that do not have an SI.
7	510(k)s NSE without SI	Number of 510(k) submissions that are closed with an NSE decision (or with an AN, DN, or ON decision where Date Received does not equal Date Final Decision) and did not have an SI.
8	Current SI Performance Percent within 60 FDA days	Number of submissions with SI within 60 FDA days (line 3) divided by the total number of submissions that either had an SI (line 3 and line 4) or did not have an SI but failed the SI goal (line 6 and line 7).

**Table 6.3 and Tables 6.3.x****510(k) Substantive Interaction Metrics – Time to Substantive Interaction - Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of 510(k) submissions accepted in this fiscal year that had an SI. Third party 510(k) submissions shall be excluded from this report.
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all 510(k) submissions with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Tables 6.4 and Tables 6.4.x****510(k) MDUFA Decision Performance Goals - Definitions**

#	Measure	Description
1	510(k)s accepted	Number of 510(k) submissions accepted in this fiscal year. Third party 510(k) shall also be included into this report.
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not SE or NSE).
3	MDUFA III Decisions (SE/NSE)	Number of submissions accepted (line 1) and closed with a MDUFA III decision (SE or NSE).
4	MDUFA III Decisions within 90 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 90 FDA days.
5	510(k)s pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review.
6	510(k) pending MDUFA III Decision over 90 FDA days	Number of submissions pending MDUFA III Decision (line 5) for more than 90 FDA Days. These submissions already failed the MDUFA III review goal.
7	Current Performance Percent within 90 FDA Days	Number of submissions with MDUFA III Decisions within 90 FDA Days (line 4) divided by the total number of submissions with MDUFA III Decisions (line 3) and pending submissions that already failed the MDUFA goal (line 6).

**Table 6.5 and Tables 6.5.x****510(k) Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Average review cycles	Average number of review cycles (after submission is accepted for review) for 510(k)s with a MDUFA decision (line 2).
2	Number with MDUFA III Decision	Number of submissions accepted in this fiscal year that had a MDUFA decision.
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.



**Table 6.6 and Tables 6.6.x****510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions - Definitions**

#	Measure	Description
1	Number Accepted	Number of 510(k) submissions accepted in this fiscal year. See definition for Accepted cohort above.
2	Number with MDUFA decision	Number submissions accepted (line 1) that also had a MDUFA decision.
3	Number of SE decisions	Number of submissions accepted (line 1) that had an SE MDUFA decision.
4	Number of NSE decisions	Number of submissions accepted (line 1) that had an NSE MDUFA decision.
5	Number of Withdrawals	Number of submissions accepted (line 1) and closed with Withdrawal (WD) final decision.
6	Number deleted	Number of submissions accepted (line 1) and closed with Delete (DE) final decision.
7	Rate of SE decisions	Number of SE decisions (line 3) divided by Number with MDUFA decision (line 2).
8	Rate of NSE decisions	Number of NSE decisions (line 4) divided by Number with MDUFA decision (line 2).
9	Rate of Withdrawals	Number of Withdrawals (line 5) divided by Number Received (line 1).
10	Rate of Deleted	Number of Deleted (line 6) divided by Number Received (line 1).

**Table 6.7 and Tables 6.7.x****510(k) Performance Metrics – Submissions Missing Performance Goals - Definitions**

#	Measure	Description
1	Number of submissions that missed the goal	Number of 510(k) submissions accepted in this fiscal year that had a MDUFA decision with more than 90 FDA days. Third Party 510(k) submissions shall also be included into this report.
2	Mean FDA days for submissions that missed goal	Mean FDA days for submissions that missed the goal (line 1).
3	Mean industry days for submissions that missed goal	Mean industry days for submissions that missed the goal (line 1).

## Section 7 510(k) Annual General Metrics

**Table 7.1 CDRH - 510(k) Annual General Metrics – 510(k)s Received by Type - Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third party 510(k) submissions shall also be included into this count.
2	Number of Traditional submissions	Number of Traditional Non-Third Party 510(k) submissions accepted in this fiscal year.
3	Number of Special submissions	Number of Special Non-Third Party 510(k) submissions accepted in this fiscal year.
4	Number of Abbreviated submissions	Number of Abbreviated Non-Third Party 510(k) submissions accepted in this fiscal year.
5	Average number of days to Accept / Refuse to Accept	Average number of days in the first RTA review cycle for Non-Third Party 510(k) submissions.
6	Number of Third Party submissions	Number of Third Party 510(k) submissions received in this fiscal year.

**Table 7.2 CDRH - 510(k) Annual Shared Outcome Goal - Definitions**

#	Measure	Description
1	Number Accepted	Total number of 510(k) submissions accepted in this fiscal year. Third-party 510(k) submissions shall also be included into this report.
2	Currently Under Review	Number of 510(k) submissions accepted (line 1) that are still under review (no final decision yet).
3	Number with Non-MDUFA decision	Number of 510(k) submissions accepted (line 1) that were closed with a Non-MDUFA decision.
4	Number with MDUFA III Decision	Total number of 510(k) submissions accepted (line 1) that had a MDUFA III decision.
5	Percent of cohort closed	Number with MDUFA decision (line 4) divided by the total of Number Under Review (line 2) and Number with MDUFA Decision (line 4).
6	Number with MDUFA III decision after trimming the upper and lower 2%	Number of 510(k) submissions with MDUFA III Decision (line 4) excluding 2% of submissions with the lowest number of Total Days to MDUFA III decision and 2% of submissions with the highest number of Total Days to MDUFA III decision.
7	Average Total Time to MDUFA III decision	Average Total Time (FDA and Industry) to MDUFA decision. If the cohort is not closed (less than 99% of 510(k) submissions have a decision) "N/A" shall be displayed instead.

## Section 8     Annual Metrics for De Novo Requests

**Table 8.1             CDRH – Annual General Metric Report for *De Novo* Requests - Definitions**

#	Measure	Description
1	Number of <i>De Novo</i> Requests Received	Total number of <i>de novo</i> requests received in this fiscal year as of the report cutoff date.
2	Number of <i>De Novo</i> Requests with Decision	Number of <i>de novo</i> requests received in this fiscal year (line 1) which have also received a final decision as of the report cutoff date.
3	Number of <i>De Novo</i> Requests with Decision Pending	Number <i>de novo</i> requests received in this fiscal year (line 1) which have not received a final decision as of the report cutoff date.
4	Average Number of Days to Decision	Average total number of days to decision (days between <i>De Novo</i> Date Received and <i>De Novo</i> Decision Date) for <i>de novo</i> requests with decision (line 2).

## Section 9 Pre-Submissions

**Table 9.1 and Tables 9.1.x Pre-Submissions Performance Metrics - Definitions**

#	Measure	Description
1	Number of all qualified Pre-Submissions received	Number of all qualified Pre-Submissions received. This include those with a type="pre-sub" either with a meeting request or written feedback requested in the fiscal year.
2	Number requesting a meeting or teleconference	Number of qualified Pre-submission received (line 1) with the Sub-Type of "Pre-Sub Meeting Request".
3	Number with meetings or teleconferences held	Number requesting a meeting or teleconference (line 2) with Actual Meeting Date populated with a value prior to the cutoff date.
4	Days to meeting	Table shall show average days from Date FDA Initial Clock Start to Actual Meeting Date as well as quintiles (20th, 40th, 60th, 80th percentiles) and the Maximum Days (100th percentile) for days to meeting days, Industry days, and Total days. The calculation includes meetings where the Actual Meeting Date is greater than the Date FDA Initial Clock Start and the Actual Meeting Date is prior to as of the cutoff date.

## Section 10 CLIA Waiver Annual Metrics

**Table 10.1 CLIA Waiver Substantive Interaction Performance Goals – Definitions**

#	Measure	Description
1	Eligible for SI	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Deleted or withdrawn prior to SI	Number of submissions with MDUFA Decision WTDR within 90 FDA days
3	SI within 90 FDA days	Number of submissions with SI action within 90 FDA days
4	SI over 90 FDA days	Number of submissions with SI action taken in more than 90 FDA days
5	SI pending within 90 FDA days	Number of submissions that are under review for not more than 90 FDA days and with no SI
6	SI pending over 90 FDA days	Number of submissions that are under review for more than 90 FDA days with no SI
7	Denial without SI	Number of submissions closed with a Denial decision and that did not have an SI prior
8	Current SI Performance Percent within 90 FDA days	Number of submissions with SI within 90 FDA days (line 3) divided by the total number of submissions Eligible for SI (line 1)

**Table 10.2 CLIA Waiver Substantive Interaction Metrics – Time to Substantive Interaction – Definitions**

#	Measure	Description
1	Number of Substantive Interactions	Number of CLIA Waiver by Applications filed in this fiscal year that had an SI
2	Average number of FDA days to Substantive Interaction	Average number of FDA days across all CLIA Waivers with SI (line 1).
3	20 <sup>th</sup> Percentile FDA days to Substantive Interaction	20 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
4	40 <sup>th</sup> Percentile FDA days to Substantive Interaction	40 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
5	60 <sup>th</sup> Percentile FDA days to Substantive Interaction	60 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
6	80 <sup>th</sup> Percentile FDA days to Substantive Interaction	80 <sup>th</sup> percentile FDA days to Substantive Interaction for submissions with SI (line 1).
7	Maximum FDA days to Substantive Interaction	Maximum FDA days (100 <sup>th</sup> percentile) to Substantive Interaction for submissions with SI (line 1).

**Table 10.3 CLIA Waiver (without Panel Review) MDUFA Decision Performance Goals) – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 180 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 180 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 180 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 180 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 180 FDA Days	Number of submissions with MDUFA III Decisions within 180 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.4 CLIA Waiver (with Panel Review) MDUFA Decision Performance Goals) – Definitions**

#	Measure	Description
1	CLIA Waiver Applications accepted	Number of CLIA Waiver by Applications that were filed in this fiscal year
2	Non-MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a non-MDUFA III decision (not Approved, Denied, or Withdrawn)
3	MDUFA III Decisions	Number of submissions accepted (line 1) and closed with a MDUFA III decision (Approved, Denied, or Withdrawn)
4	MDUFA III Decisions within 330 FDA Days	Number of submissions with MDUFA III decisions (line 3) made within 330 FDA days
5	CLIA Waiver Applications pending MDUFA III Decision	Number of submissions accepted (line 1) and still under review
6	CLIA Waiver Applications pending MDUFA III Decision over 330 FDA days	Number of submissions pending MDUFA III Decision (line5) for more than 330 FDA days. These submissions already failed the MDUFA III Decision goal.
7	Current Performance Percent within 330 FDA Days	Number of submissions with MDUFA III Decisions within 330 FDA days (line 4) divided by the total number of submissions with MDUFA III decisions (line 3) and pending submissions that already failed the MDUFA III Decision goal (line 6)

**Table 10.5 CLIA Waiver (without Panel Review) Time to MDUFA Decision – Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn)
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

**Table 10.6**      **CLIA Waiver (with Panel Review) Time to MDUFA Decision - Definitions**

#	Measure	Description
1	Number with MDUFA decision	Number of submissions accepted in this fiscal year that had a MDUFA III decision (Approved, Denied, or Withdrawn)
	Days to MDUFA Decision	Table shall show Average Days to MDUFA III decision as well as quintiles (20 <sup>th</sup> , 40 <sup>th</sup> , 60 <sup>th</sup> , 80 <sup>th</sup> percentiles) and the Maximum Days (100 <sup>th</sup> percentile) for FDA days, Industry days, and Total days.

## Section 11 IDE Performance Metrics

Table 11.1 IDE Performance Metrics

#	Measure	Description
1	Number of IDEs received	Number of IDEs received in the fiscal year.
2	Average number of cycles to approval or conditional approval of the IDE	The average number of cycles including the original submission and amendments that were submitted prior to the approval or conditional approval of an IDE.
3	Average number of amendments prior to approval or conditional approval of the IDE	The average number of amendments, to include only those amendments that were submitted to address deficiencies in the disapproval letter.



**Quarterly Update on  
Medical Device Performance Goals  
----MDUFA III CBER Performance Data ----  
Action through 31 March 2013**

## Section 1 PMA Original and Panel Track Supplements - Center Level

**Table 1.1 CBER – PMA Original and Panel Track Supplements – Acceptance and Filing Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	1	3			
Closed before RTA action	0	0			
Number Accepted	1	1			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	0	1			
Number Not Accepted for Filing Review	0	1			
Rate of submissions not accepted for filing review	0.0%	33.3%			
Completed RTF	0	0			
Number Not Filed	0	2			
Rate of submissions Not Filed	0.0%	66.7%			

**Table 1.2 CBER – PMA Originals & Panel-Track Supplements Substantive Interaction Performance Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	1	2			
SI within 90 FDA days	0	1			
SI over 90 FDA days	1	0			
SI pending within 90 FDA days	0	1			
SI pending over 90 FDA days	0	0			
Closed without SI	0	0			
Current SI Performance Percent within 90 FDA days	0.0%	100.0%			

**Table 1.3 CBER – PMA Originals and Panel Track Supplements Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	1	1			
Average number of FDA days to Substantive Interaction	101	88			
20th Percentile FDA days to Substantive Interaction	101	88			
40th Percentile FDA days to Substantive Interaction	101	88			
60th Percentile FDA days to Substantive Interaction	101	88			
80th Percentile FDA days to Substantive Interaction	101	88			
Maximum FDA days to Substantive Interaction	101	88			

**Table 1.4 CBER – PMA Originals & Panel-Track Supplements (without Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	70% within 180 FDA days	80% within 180 FDA days	80% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days
Number of PMAs filed	0	1			
Non-MDUFA III Decisions	0	1			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 180 FDA Days	0	0			
PMAs pending MDUFA III Decision	0	1			
PMAs pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	0.0%	0.0%			

**Table 1.5 CBER – PMA Originals & Panel-Track Supplements (with Panel Review) MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	50% within 320 FDA days	70% within 320 FDA days	80% within 320 FDA days	80% within 320 FDA days	90% within 320 FDA days
Number of PMAs filed	1	0			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	0	0			
MDUFA III Decisions within 320 FDA Days	0	0			
PMAs pending MDUFA III Decision	1	0			
PMAs pending MDUFA III Decision over 320 FDA days	0	0			
Current Performance Percent within 320 FDA Days	0.0%	0.0%			

**Table 1.6 CBER – PMA Original and Panel Track Supplements (without Panel Review)**  
**Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0			
<b>Average FDA days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile FDA days to MDUFA III decision	0	0			
40th Percentile FDA days to MDUFA III decision	0	0			
60th Percentile FDA days to MDUFA III decision	0	0			
80th Percentile FDA days to MDUFA III decision	0	0			
Maximum FDA days to MDUFA III decision	0	0			
<b>Average Industry days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	0	0			
Maximum Industry days to MDUFA III decision	0	0			
<b>Average Total days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Total days to MDUFA III decision	0	0			
40th Percentile Total days to MDUFA III decision	0	0			
60th Percentile Total days to MDUFA III decision	0	0			
80th Percentile Total days to MDUFA III decision	0	0			
Maximum Total days to MDUFA III decision	0	0			

**Table 1.7 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Number with MDUFA III decision	0	0			
<b>Average FDA days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile FDA days to MDUFA III decision	0	0			
40th Percentile FDA days to MDUFA III decision	0	0			
60th Percentile FDA days to MDUFA III decision	0	0			
80th Percentile FDA days to MDUFA III decision	0	0			
Maximum FDA days to MDUFA III decision	0	0			
<b>Average Industry days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	0	0			
80th Percentile Industry days to MDUFA III decision	0	0			
Maximum Industry days to MDUFA III decision	0	0			
<b>Average Total days to MDUFA III decision</b>	<b>0</b>	<b>0</b>			
20th Percentile Total days to MDUFA III decision	0	0			
40th Percentile Total days to MDUFA III decision	0	0			
60th Percentile Total days to MDUFA III decision	0	0			
80th Percentile Total days to MDUFA III decision	0	0			
Maximum Total days to MDUFA III decision	0	0			

**Table 1.8 CBER – PMA Originals and Panel Track Supplements (without Panel Review)  
Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	0	1			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	0.0%			
Rate of Not Approvable	0.0%	0.0%			

**Table 1.9 CBER – PMA Original and Panel Track Supplements (with Panel Review) Performance Metrics – Rate of Withdrawal and Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	0			
Number with MDUFA decision	0	0			
Number of Withdrawals	0	0			
Number of Not Approvable	0	0			
Rate of Withdrawals	0.0%	0.0%			
Rate of Not Approvable	0.0%	0.0%			

**Table 1.10 CBER – PMA Original and Panel Track Supplements (without Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

**Table 1.11 CBER – PMA Original and Panel Track Supplements (with Panel Review)  
Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

## Section 2 PMA 180 Day Supplements - Center Level

**Table 2.1 CBER – PMA 180 Day Supplements Substantive Interaction Goals**

Substantive Interaction (SI) Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 90 FDA days	75% SI within 90 FDA days	85% SI within 90 FDA days	95% SI within 90 FDA days	95% SI within 90 FDA days
Eligible for SI	2	2			
SI within 90 FDA days	2	0			
SI over 90 FDA days	0	0			
SI pending within 90 FDA days	0	2			
SI pending over 90 FDA days	0	0			
Closed without SI	1	0			
Current SI Performance Percent within 90 FDA days	100.0%	0.0%			

**Table 2.2 CBER – PMA 180 Day Supplements MDUFA Decision Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	85% within 180 FDA days	90% within 180 FDA days	90% within 180 FDA days	95% within 180 FDA days	95% within 180 FDA days
Supplements received	3	2			
Non-MDUFA III Decisions	1	0			
MDUFA III Decisions	2	0			
MDUFA III Decisions within 180 FDA Days	2	0			
Supplements pending MDUFA III Decision	0	2			
Supplements pending MDUFA III Decision over 180 FDA days	0	0			
Current Performance Percent within 180 FDA Days	100.0%	0.0%			

**Table 2.3 CBER – PMA 180 Day Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	2			
Number with MDUFA decision	2	0			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.0%	0.0%			



**Table 2.4 CBER – PMA 180 Day Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean Industry days for submissions that missed goal	0	0			

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### Section 3 PMA Real Time Supplements - Center Level Metrics

**Table 3.1 CBER – Real Time PMA Supplements MDUFA Performance Goals**

Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	90% within 90 FDA days	90% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days	95% within 90 FDA days
Supplements received	3	1			
Non-MDUFA III Decisions	0	0			
MDUFA III Decisions	3	1			
MDUFA III Decisions within 90 FDA Days	3	1			
Supplements pending MDUFA III Decision	0	0			
Supplements pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100.0%	100.0%			

**Table 3.2 CBER – Real Time PMA Supplements Performance Metrics – Rate of Not Approvable**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	3	1			
Number with MDUFA decision	3	1			
Number of Not Approvable	0	0			
Rate of Not Approvable	0.0%	0.0%			

**Table 3.3 CBER – Real Time PMA Supplements Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean Industry days for submissions that missed goal	0	0			

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## Section 5 PMA Annual Metrics and Goals

**Table 5.1 CBER – PMAs (All Review Tracks) Annual General Metrics – PMAs Received by Type**

PMA Submissions Received	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Premarket Report Submissions	0	0			
Original PMAs (Panel) – Priority	0	0			
Original PMAs (No Panel) – Priority	0	0			
Original PMAs (Panel) – Non-Priority	1	0			
Original PMAs (No Panel) – Non-Priority	0	3			
Panel-Tracked Supplements (Panel) – Priority	0	0			
Panel-Tracked Supplements (No Panel) – Priority	0	0			
Panel-Tracked Supplements (Panel) – Non-Priority	0	0			
Panel-Tracked Supplements (No Panel) – Non-Priority	0	0			
PMA Modules	7	1			
180-Day Supplements	3	2			
Real-Time Supplements	3	1			

**Table 5.2 CBER – PMA Originals and Panel Tracked Supplements Annual Shared Outcome Goal – Percent Cohorts Closed**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Filed	1	1			
Number with a decision (MDUFA or Non-MDUFA)	1	1			
% of FY closed	0.0%	0.0%			

## Section 6 510(k) Center Level Metrics

**Table 6.1 CBER – 510(k) Acceptance Review Decision**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Received	59	26			
Closed before RTA action	6	1			
Number Accepted	46	20			
Number without a RTA Review and > 15 Days since Date Received	0	0			
Number without a RTA Review and <= 15 Days since Date Received	1	1			
Number Not Accepted	6	4			
Rate of submissions not accepted for review	10.2%	15.4%			

**Table 6.2 CBER – 510(k) Substantive Interaction Performance Goals**

Substantive Interaction (SI) Performance Goals:	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
	65% SI within 60 FDA days	75% SI within 60 FDA days	85% SI within 60 FDA days	95% SI within 60 FDA days	95% SI within 60 FDA days
Eligible for SI	46	20			
SI within 60 FDA days	40	12			
SI over 60 FDA days	6	0			
SI pending within 60 FDA days	0	7			
SI pending over 60 FDA days	0	1			
510(k)s NSE without SI	0	0			
Current SI Performance Percent within 60 FDA days	87.0%	92.3%			

**Table 6.3 CBER – 510(k) Substantive Interaction Metrics – Time to Substantive Interaction**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Substantive Interactions	46	12			
Average number of FDA days to Substantive Interaction	49	49			
20th Percentile FDA days to Substantive Interaction	29	28			
40th Percentile FDA days to Substantive Interaction	43	50			
60th Percentile FDA days to Substantive Interaction	57	56			
80th Percentile FDA days to Substantive Interaction	59	58			
Maximum FDA days to Substantive Interaction	90	60			

**Table 6.4 CBER – 510(k) MDUFA Decision Performance Goals**

<b>Performance Goals:</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	<b>91% within 90 FDA days</b>	<b>93% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>	<b>95% within 90 FDA days</b>
510(k)s accepted	46	20			
Non-MDUFA III Decisions	44	6			
MDUFA III Decisions (SE/NSE)	33	7			
MDUFA III Decisions within 90 FDA Days	33	7			
510(k)s pending MDUFA III Decision	7	13			
510(k) pending MDUFA III Decision over 90 FDA days	0	0			
Current Performance Percent within 90 FDA Days	100.0%	100.0%			

**Table 6.5 CBER – 510(k) Time to MDUFA Decision**

<b>Performance Metric</b>	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
Average review cycles	1.61	1.14			
Number with MDUFA III decision	33	7			
<b>Average FDA days to MDUFA III decision</b>	69	60			
20th Percentile FDA days to MDUFA III decision	28	21			
40th Percentile FDA days to MDUFA III decision	80	28			
60th Percentile FDA days to MDUFA III decision	86	81			
80th Percentile FDA days to MDUFA III decision	89	85			
Maximum FDA days to MDUFA III decision	90	89			
<b>Average Industry days to MDUFA III decision</b>	63	5			
20th Percentile Industry days to MDUFA III decision	0	0			
40th Percentile Industry days to MDUFA III decision	0	0			
60th Percentile Industry days to MDUFA III decision	36	0			
80th Percentile Industry days to MDUFA III decision	95	0			
Maximum Industry days to MDUFA III decision	370	36			
<b>Average Total days to MDUFA III decision</b>	132	65			
20th Percentile Total days to MDUFA III decision	28	21			
40th Percentile Total days to MDUFA III decision	87	28			
60th Percentile Total days to MDUFA III decision	109	81			
80th Percentile Total days to MDUFA III decision	182	85			
Maximum Total days to MDUFA III decision	460	123			

**Table 6.6 CBER – 510(k) Performance Metrics – Rate of SE, NSE, Withdrawal and Delete Decisions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	46	20			
Number with MDUFA decision	33	7			
Number of SE decisions	31	7			
Number of NSE decisions	2	0			
Number of Withdrawals	12	1			
Number deleted	0	0			
Rate of SE decisions	68.9%	87.5%			
Rate of NSE decisions	4.4%	0.0%			
Rate of Withdrawals	26.7%	12.5%			
Rate of Deleted	0.0%	0.0%			

**Table 6.7 CBER – 510(k) Performance Metrics – Submissions Missing Performance Goals**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of submissions that missed the goal	0	0			
Mean FDA days for submissions that missed goal	0	0			
Mean industry days for submissions that missed goal	0	0			

## Section 7 510(k) Annual General Metrics

**Table 7.1 CBER – 510(k) Annual General Metrics – 510(k)s Received by Type**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	46	20			
Number of Traditional submissions	33	16			
Number of Special submissions	9	4			
Number of Abbreviated submissions	4	0			
Average number of days to Accept / Refuse to Accept	13	13			
Number of Third Party submissions	0	0			

**Table 7.2 CBER - 510(k) Annual Shared Outcome Goal**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number Accepted	46	20			
Currently Under Review	7	13			
Number with Non-MDUFA Decision	44	6			
Number with MDUFA III Decision	33	7			
Percent of cohort closed	76.3%	30.8%			
Number with MDUFA III decision after trimming the upper and lower 2%	21	5			
Average Total Time to MDUFA III decision	132	65			



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## Section 8 De Novo Petitions

**Table 8.1 CBER – Annual General Metric Report for De Novo Classification Petitions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of De Novo Petitions Received	2	0			
Number of De Novo Petitions with Decision	1	0			
Number of De Novo Petitions with Decision Pending	1	0			
Average Number of Days to Decision	366	0			

## Section 9 Pre-Submissions

### Section 9 Pre-Submission Center Level Metrics

**Table 9.1 CBER – Pre-Submission Center Level Metrics**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of all qualified Pre-Submissions received	44	23			
Number requesting a meeting or teleconference	34	19			
Number with meetings or teleconferences granted	31	19			
Number with meeting granted and industry cancelled	13	2			
Number with meeting granted and FDA cancelled	0	0			
Number with meeting granted and pending within timeframe	0	11			
Number with meeting granted and pending outside timeframe	1	1			
Number with meetings or teleconferences held	15	5			
Average days to meeting	65	86			
20th Percentile days to meeting	55	62			
40th Percentile days to meeting	58	89			
60th Percentile days to meeting	61	91			
80th Percentile days to meeting	70	92			
Maximum days to meeting	122	98			

**BLAs****CBER – Annual General Metric Report for BLAs**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard BLAs Filed	9	0			
Number of Standard BLA First Actions less than or equal to 10 months	9	0			
Number of Standard BLA First Actions greater than 10 months	0	0			
Number of Standard BLAs Pending	0	5			
Number of Priority BLA Filed	0	0			
Number of Priority BLA First Actions less than or equal to 10 months	0	0			
Number of Priority BLA First Actions greater than 10 months	0	0			
Number of Priority BLAs Pending	0	0			

**BLA Efficacy Supplements****CBER – Annual General Metric Report for BLA Efficacy Supplements**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard Efficacy Supplements Filed	0	0			
Number of Standard Efficacy Supplements First Actions less than or equal to 10 months	0	0			
Number of Standard Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Standard Efficacy Supplements Pending	0	10			
Number of Priority Efficacy Supplements Filed	0	0			
Number of Priority Efficacy Supplements First Actions less than or equal to 10 months	0	0			
Number of Priority Efficacy Supplements First Actions greater than 10 months	0	0			
Number of Priority Efficacy Supplements Pending	0	0			

**BLA Prior Approval Manufacturing Supplements**  
**CBER – Annual General Metric Report for BLA PAS Supplements**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Standard PAS Supplements Filed	20	1			
Number of Standard PAS Supplements First Actions less than or equal to 4 months	20	1			
Number of Standard PAS Supplements First Actions greater than 4 months	0	0			
Number of Standard PAS Supplements Pending	0	0			

**BLA/BLA Resubmissions**  
**CBER – Annual General Metric Report for BLA/BLA Resubmissions**

Performance Metric	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Number of Class 1 Resubmissions Received	10	5			
Number of Class 1 Resubmission Actions less than or equal to 2 months	10	0			
Number of Standard Class 1 Resubmission First Actions greater than 2 months	0	0			
Number of Class 1 Resubmissions Pending	0	5			
Number of Class 2 Resubmissions Received	0	1			
Number of Class 2 Resubmission Actions less than or equal to 6 months	0	0			
Number of Class 2 Resubmission Actions greater than 6 months	0	0			
Number of Class 2 Resubmissions Pending	0	1			

<b>FY 2014 Medical Device User Fee Collections</b> <b>as of March 31, 2014</b> <sup>/1, 2</sup> Excludes Unearned Fees					
	<b>Receipts</b>	<b>Refunds</b>	<b>Net</b>	<b>Authorized</b>	<b>% of Authorized</b>
Registration Fees	\$75,740,106	\$181,318	\$75,558,788		
Application Fees	\$22,520,920	\$146,652	\$22,374,268		
<b>Total</b>	<b>\$98,261,026</b>	<b>\$327,970</b>	<b>\$97,933,056</b>	<b>\$115,055,000</b>	<b>85%</b>

<b>Medical Device User Fee Collection History</b> <sup>/3</sup> Excludes Unearned Fees, Includes Refunds					
MD I	<b>FY 2003</b>	<b>FY 2004</b>	<b>FY 2005</b>	<b>FY 2006</b>	<b>FY 2007</b>
	\$21,620,549	\$26,280,073	\$31,814,416	\$35,047,878	\$28,719,027
MD II	<b>FY 2008</b>	<b>FY 2009</b>	<b>FY 2010</b>	<b>FY 2011</b>	<b>FY 2012</b>
	\$47,519,348	\$55,703,707	\$62,737,664	\$69,551,822	\$65,033,161
MD III	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>	<b>FY 2016</b>	<b>FY 2017</b>
	\$96,752,649				

*Notes:*

<sup>/1</sup> Figures are based on Q2 data; subject to revision.

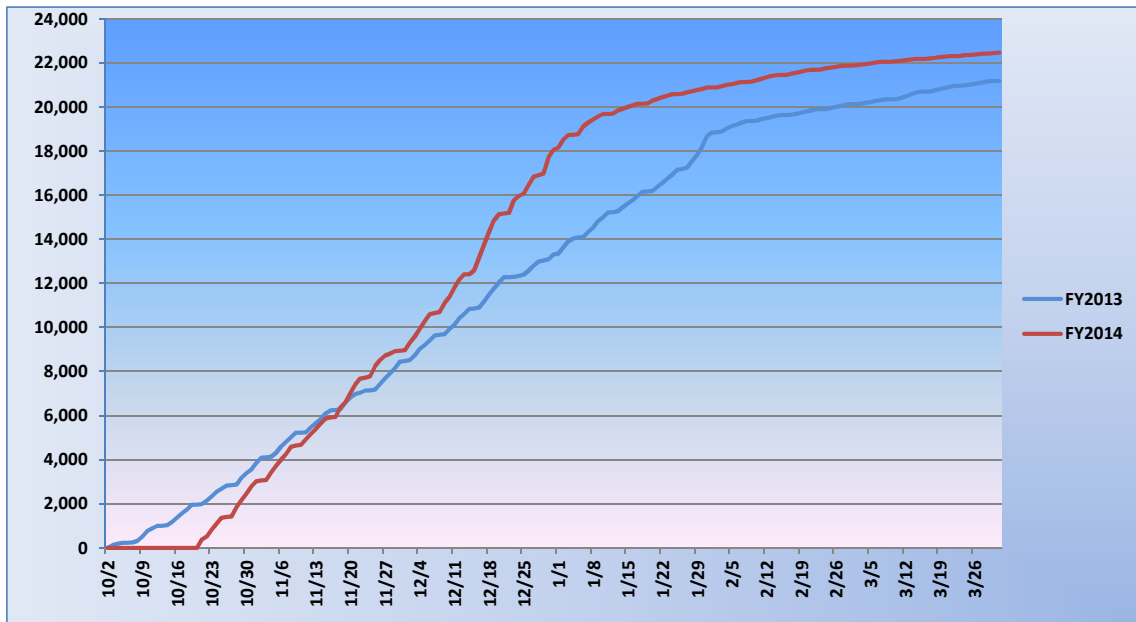
<sup>/2</sup> Collections in this section are attributed to the authorized revenue ceiling for Cohort Year 2014.

<sup>/3</sup> Collections in this section are attributed to the authorized revenue ceiling of the Cohort Year listed.

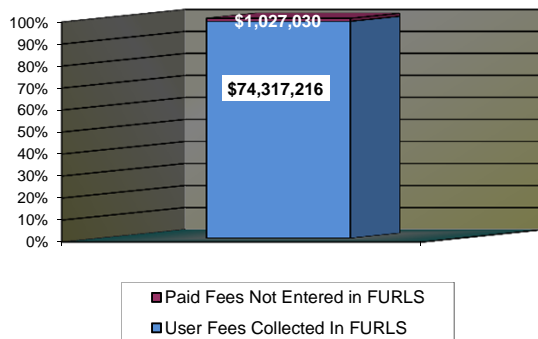
## MDUFA III, Registrations, Second Quarter Summary FY2014

Registrations by Type	FY14 to Date (Currently Active)			FY2013 Year End Active Totals			Difference Thru 3/31/13
	Domestic	Foreign	Total	Domestic	Foreign	Total	
Manufacturer/ Complaint File Handler	5,461	8,033	13,494	5,517	8,376	13,893	-399
Contract Manufacturer	817	1,000	1,817	786	1,014	1,800	17
Contract Sterilizer	73	109	182	73	107	180	2
Specification Developer	1,568	369	1,937	1,661	363	2,024	-87
Reprocessor of Single Use Devices	20	1	21	21	2	23	-2
U.S. Manufacturer of Export Only Devices	124		124	127		127	-3
Repackager/Relabeler	1,074	148	1,222	1,164	169	1,333	-111
Remanufacturer	22	15	37	28	19	47	-10
Foreign Exporter/Private Label Distributor	0	569	569	0	630	630	-61
Initial Importer	2,940		2,940	3,272		3,272	-332
Unknown	8	6	14	15	8	23	-9
<b>Total:</b>	<b>12,107</b>	<b>10,250</b>	<b>22,357</b>	<b>12,664</b>	<b>10,688</b>	<b>23,352</b>	<b>-995</b>

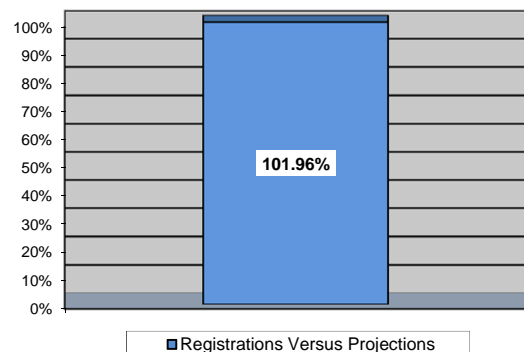
**Registration Progress - FY2013 Versus FY2014**



**User Fees Collected Versus User Fees Paid in Dollars**



**User Fee Progress - Percent Collected Versus Projections**  
Goals - \$72,886,000 fees; 22,000 Registrations



# **Staff College Internal Training Summary Report**

**From 10/1/2013 to 3/31/2014**



As of: 4/28/2014

## **Q2 FY14 (*October 1, 2013 – March 31, 2014*) MDUFA-Related Training**

FDA continues to invest in internal and external training opportunities supporting the medical device review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As medical device reviews grow increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between October 1, 2013 and March 31, 2014. Staff College offered 293 learning events addressing reviewer training, new scientific technologies, law, regulation and guidance updates, and leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. Overall, 76% (1143) of the approximately 1500 Center staff participated in training and on average attended 4 ( $4206 \div 1143$ ) learning events.

**Table X: MDUFA Q2 FY14 CDRH Staff College Internal Training**

Category	# of Learning Events	Total # of Completions	Total Contact Hours	Examples of Training Conducted/Attended Between 10/1/13 3/31/2014
<b>Regulatory and Law (LAW)</b>	169	1307	3867	<ul style="list-style-type: none"> <li>• Reviewer Certification Program <ul style="list-style-type: none"> <li>– Introduction to Medical Device Law</li> <li>– Basic Food and Drug Law</li> </ul> </li> <li>• Fundamentals of Standards</li> <li>• Compiling the Administrative File for Premarket Submission Decisions – Online</li> <li>• Foundations of Plain Language</li> </ul>
➤ <b>MDUFA III Training*</b>	31	102	254	<ul style="list-style-type: none"> <li>• <i>Introduction to MDUFA III</i></li> <li>• <i>510(k)s</i></li> <li>• <i>PMA's</i></li> <li>• <i>Pre-Submissions</i></li> <li>• <i>CLIA Waivers</i></li> <li>• <i>Electronic Workload Management</i></li> </ul>
➤ <b>ELP**</b>	18	179	1398	
<b>Leadership Education and Development (LED)</b>	20	285	1595	<ul style="list-style-type: none"> <li>• CDRH New Manager Orientation Program</li> <li>• CDRH Management Administrative Learning Forum's <ul style="list-style-type: none"> <li>• Use or Lose Leave</li> <li>• PMAP Closeout and Establish</li> </ul> </li> </ul>
➤ <b>LEAD***</b>	15	63	414	<ul style="list-style-type: none"> <li>• <i>Fundamentals of Strategic Planning</i></li> <li>• <i>Critical Thinking and Creative Problem Solving for Managers</i></li> <li>• <i>CDRH Employee/Labor Relations for Managers</i></li> <li>• <i>PMAP Overview</i></li> <li>• <i>CDRH New Manager Orientation Program</i></li> </ul>
<b>Professional Development (PRO)</b>	34	1000	3082	<ul style="list-style-type: none"> <li>• Critical TOP Thinking</li> <li>• Effective Briefing and Presentation Skills</li> <li>• Recall Classification Processes Mentoring Session</li> <li>• Fundamentals of Project Management</li> <li>• Understanding the Center's Budget Decisions</li> </ul>
➤ <b>New Employee Orientation (NEO)****</b>	2	44	308	<ul style="list-style-type: none"> <li>• <i>New Employee Orientation: Discover the Mission, Embrace the Vision</i></li> </ul>
<b>Science (SCI)</b>	70	1614	5709	<ul style="list-style-type: none"> <li>• CDRH Science Sharing Seminars</li> <li>• UDI: A Foundation of Health Informatics Initiatives - Online</li> <li>• Basics of Flow Cytometry</li> <li>• Statistics for Clinical Trials with Application to Medical Devices</li> </ul>
<b>Total:</b>	<b>293</b>	<b>4206</b>	<b>14253</b>	

\* The MDUFA III data has been incorporated under the Law category within the subsequent data charts.

\*\*The ELP data has been incorporated under the Law category within the subsequent data charts.

\*\*\*The LEAD data has been incorporated under the Leadership category within the subsequent data charts.

\*\*\*\*The NEO data has been incorporated under the Professional Development category within the subsequent data charts.



## Leadership Readiness Program (LRP) Graduates ROI Update 2013

LRP Program Year	# of Enrolled Participants	# of Participant Completions
<b>2006-2007</b>	OIVD=3 ODE =13 Total = 16	OIVD = 3 ODE = 12 Total = 15
<b>2008-2009</b>	OIVD=3 ODE = 10 Total = 30	OIVD = 3 ODE = 10 Total = 29
<b>2010-2011</b>	OIVD = 3 ODE = 9 Total = 20	OIVD = 3 ODE = 8 Total = 19
<b>2012-2013*</b>	OIR = 3 ODE = 6 Total = 20	OIR = 3 ODE = 6 Total = 20
<b>Sub total</b>	<b>OIR=12</b> <b>ODE =38</b> <b>Total = 86</b>	<b>OIR = 12</b> <b>ODE = 36</b> <b>Total = 83</b>

**\*\*The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) is now the Office of In Vitro Diagnostics and Radiological Health (OIR).**

# ODE and OIR Reviewer Certification Program (RCP) Training Data

## *September 2013 – March 2014*

Category	# of Learning Events	Total # of Completions	Total Contact Hours	Examples of Training Conducted/Attended
RCP	17	274	2532	<ul style="list-style-type: none"> <li>– Introduction to Medical Devices</li> <li>– How to Write Deficiencies in Four-Part Harmony</li> <li>– How to Write Effective Pre-market Consulting Reviews</li> <li>– Effective Communication Skills for Scientific and Technical Professionals</li> <li>– Basic Food and Drug Law</li> <li>– Freedom of Information (FOI) Training</li> <li>– The 7 Habits of Highly Effective People</li> <li>– 510(k) Essentials Online</li> <li>– MDUFA III Training</li> <li>– Introduction to IDE Webcast</li> </ul>

## RCP Training Data by Office

### *September 2013 – March 2014*

Cohort	Office	Total # of Participants	Hours Completed
Fall 2013	ODE	21	1352
	OIR	10	554
Spring 2014	ODE	8	342
	OIR	8	284

## FY12 Experiential Learning Program (ELP)

*October 2013 – March 2014*

Category	# of Learning Events	Total # of Completions	Total Contact Hours	Examples of Training Conducted/Attended
ELP	18	179	1398	<p>Topic areas addressed during the ELP site visits include:</p> <ul style="list-style-type: none"> <li>– Orthopedic and Dental Device Coatings</li> <li>– Implantable Pacemakers/Defibrillators</li> <li>– Patient-matched Technologies</li> <li>– Clinical Trials</li> <li>– Microbiology Manufacturing</li> <li>– Molecular Devices</li> <li>– Diabetes Care Devices</li> </ul>

FY 2014 Experiential Learning Program (ELP) by Office					
Office	Quarter	# of Site Visits	# of Training Days	# of Attendees	Training Conducted
ODE	Q1	4	6	42	<ul style="list-style-type: none"> <li>– Clinical use of plastic and reconstructive devices</li> <li>– Management of clinical trials for medical devices</li> </ul>
	Q2	7	15	78	<ul style="list-style-type: none"> <li>– Manufacturing of contact lenses</li> <li>– Clinical use of cardiovascular devices</li> <li>– Management of clinical trials for medical devices</li> </ul>
OIR	Q1	2	3.5	18	<ul style="list-style-type: none"> <li>– Manufacturing of microbiology devices</li> <li>– Manufacturing and development of molecular/immunology devices</li> </ul>
	Q2	5	8	41	<ul style="list-style-type: none"> <li>– Manufacturing, development, and assessment of cytology/pathology devices</li> <li>– Manufacturing of chemistry devices</li> </ul>

## Q2 FY14 ODE and OIR Leadership Development Training

*October 1, 2013 – March 31, 2014*

Category	# of Learning Events	Total # of Completions	Total Contact Hours	Examples of Training Conducted/Attended
LEAD	15	63	414	<ul style="list-style-type: none"> <li>• CDRH Employee/Labor Relations for Managers</li> <li>• Fundamentals of Strategic Planning</li> <li>• Critical Thinking and Creative Problem Solving for Managers</li> <li>• CDRH Managers Administrative Learning Forum: PMAP Close Out &amp; Establishment</li> <li>• CDRH Customer Service Training</li> <li>• Feedback Skills for Everyday Managers</li> <li>• Improving Communication Effectiveness</li> <li>• Understanding Center Budget Decisions for Managers</li> </ul>

	Office	Total # of Managers and Supervisors*	# of Training Participants	Hours Completed	Office Participation Percentage
Q1 + Q2	ODE	56	25	300	45%
	OIR	30	13	114	43%

# MDUFA III Quarterly Performance Update

## Independent Assessment of Medical Device Review Process

2nd Quarter FY 2014 Status – April 29, 2014

### Objectives

Pursuant to the Performance Goals and Procedures adopted under the 2012 Medical Device User Fee Amendments (MDUFA III), FDA agreed to participate with the device industry in a comprehensive assessment of the process for the review of device applications.

This requirement is to conduct a comprehensive assessment of FDA premarket review processes for medical devices and to identify opportunities for improvement that will significantly impact the review of device premarket applications. Primary objectives include:

#### Phase 1:

- Identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards
- In-depth analyses of the elements of the review process in order to identify best practices and opportunities for improvement, including root cause analyses of selected significant factors
- Assessment of resource allocation to premarket device reviews across FDA
- Development of implementation plans for selected recommendations
- Development of metrics to ensure successful implementation of recommendations and demonstrate achievement of expected results

#### Phase 2:

- Evaluation of the implementation of selected recommendations

### Timeline

Milestone	Planned	Status
<b>FY 2013</b>		
Publish Federal Register notice	December 2012	Completed
Award contract	May 2013	Completed June 2013
Contract kickoff meeting between FDA and contractor	June 2013	Completed July 2013
Final workplan for Phase 1	July 2013	Completed August 2013
Report on preliminary findings and high-priority recommendations	December 2013	Completed December 2013
<b>FY 2014</b>		
Implementation plan for high-priority recommendations	June 2014	On target
Final report on complete findings and recommendations	June 2014	On target
Implementation plan for final recommendations	December 2014	

Milestone	Planned	Status
<b>FY 2015</b>		
Phase 2 kickoff meeting between FDA and contractor	October 2014	
Final workplan for Phase 2	November 2014	
<b>FY 2016</b>		
Final evaluation report	February 1, 2016	

**Progress to-date:**

- Established Project Advisory Group (PAG) – Kickoff Meeting held July 12, 2012
- Established Technical Advisory Group (TAG) – 1<sup>st</sup> Meeting held September 12, 2012
- Drafted Assessment Statement of Work for FDA clearance – October 11, 2012
- Published SOW for industry and public comment – December 18, 2012
- Spoke with industry representatives regarding SOW feedback – January 29, 2013
- Received comments from Federal Register notice – February 4, 2013
- Finalized SOW based on feedback from Federal Register notice – March 25, 2013
- Issued request for proposal – April 19, 2013
- Awarded task order to Booz Allen Hamilton (BAH) – June 11, 2013
- Held kick-off meeting – July 1, 2013
- Received draft workplan – July 19, 2013
- Final workplan – August 2, 2013
- Focus group with Medical Device Industry representatives – August 17, 2013
- Report on preliminary findings and high-priority recommendations – December 11, 2013

**Progress from 2nd Quarter FY 2014:**

- BAH meeting with Medical Device Industry representatives – January 17, 2014
- BAH benchmarking discussions with U.S. Patent and Trademark Office – February 2014
- Contractual progress reports and updates from BAH assessment team – Ongoing

**Planned Progress prior to 3rd Quarter Meeting FY 2014:**

- Contractual progress reports and updates from BAH assessment team – Ongoing
- Final report on complete findings and recommendations – June 11, 2014
- Implementation plan for high-priority recommendations – June 11, 2014